PCC IM-PACT 2021

POLIT CASE COMPETITION

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Opening

Over the past century, one of the most pressing research areas has been to find a cure for cancer. Currently, one in six deaths worldwide is due to cancer, making it one of the leading causes of loss of life. In Denmark, around 43.000 persons are diagnosed with cancer every year, and a third of all Danes are currently expected to develop cancer before the age of 75. In fact, on average, every 12th minute, a new patient is diagnosed with cancer in Denmark, and every 33rd minute, cancer is the cause of death for yet another Danish patient. Across all cancer types, only roughly two-thirds of patients survive longer than five years once diagnosed.

However, research has come a long way in the fight against cancer. A novel form of revolutionary cell therapy treatment, generally known as CAR-T treatment, has shown substantial effects in clinical studies and has the potential to be curative of a range of specific cancer types, thus outsmarting the otherwise extremely resilient disease.

> *CAR-T is a huge technological and medicinal step into the future, and will push the boundaries for how we treat cancer.*
>
> - **Ulrik Overgaard,**
> Chief Physician, Department of Hematology, Rigshospitalet

These research advances within CAR-T treatment have given pharmaceutical companies an unprecedented set of tools for crafting exceedingly effective treatments within oncology and hematology. For the same reason, the world's largest pharmaceutical companies are investing heavily in research and development within CAR-T, and we stand on the brink of technological progress that will lead to new and more effective ways of fighting cancer. And due to these pioneering pharmaceutical companies, the first CAR-T treatments are already available.

The challenge

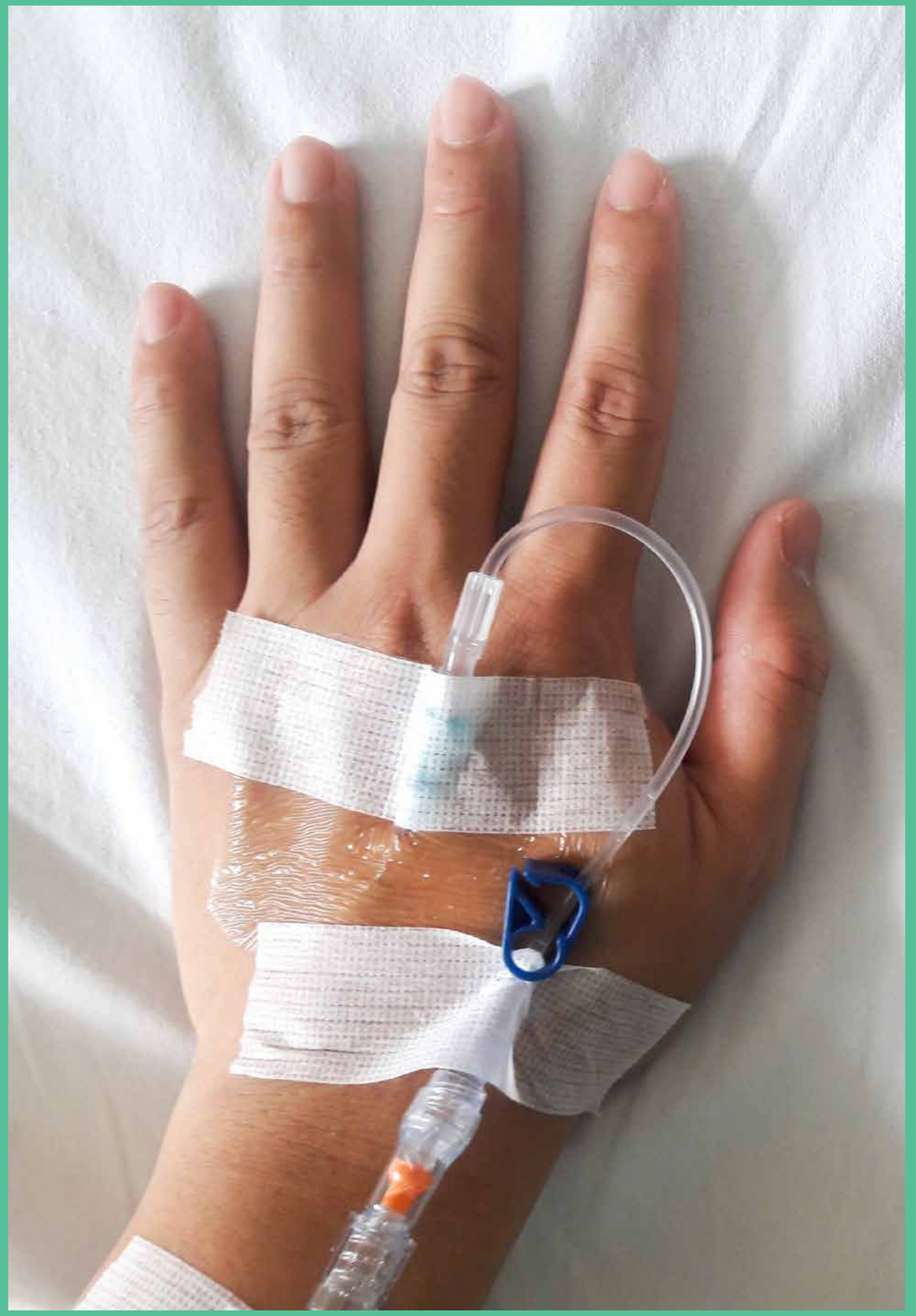
Despite having developed potentially life-saving cancer treatments, pharmaceutical companies are facing reluctance from national health authorities to be willing to pay for the revolutionary treatments, with the consequence that only very few CAR-T treatments are offered to cancer patients at public hospitals today. One main challenge is that the CAR-T treatments have been developed so recently that clinical studies do not go very far back in time, which leads to a large degree of uncertainty around the long-term benefits of the treatment.

In addition, the costs of these new treatments are often high. This is partly because of the high level of sophistication in the treatment itself, and partly because pharmaceutical companies charge a high price for the treatment. The high price is due to a number of reasons. One of these is that the marginal costs of offering the treatment are high compared to conventional treatments. A second and slightly more complex reason is that pharmaceutical companies need to consider their ability to recoup their investments and continuously develop innovative treatments in the future, which requires a certain profit margin when pricing the treatment.

Lastly, as opposed to many other types of treatment, CAR-T is a one-time procedure, and the effect on the individual patient is unknown until after the treatment has been administered. Thus, if the treatment is unsuccessful for a given patient, all of the costs will already have been paid and potentially will have been paid in vain. This is a clear difference from regular treatments – e.g. chemotherapy – where it is possible to discontinue treatment if the effects are weak, thereby limiting expenses.

In conclusion, the high price of a one-time treatment coupled with a large degree of uncertainty of the long-term benefits makes national health authorities hesitant to be willing to pay for the treatment, potentially keeping curative and life-extending treatments from patients.

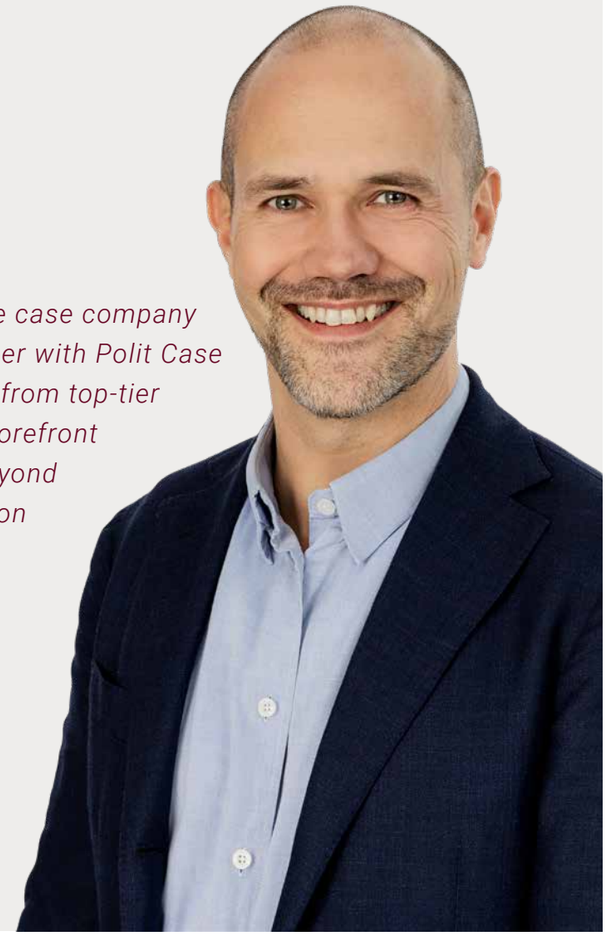
In 2019, the Danish Medicines Council rejected two applications of adopting CAR-T treatments as standard treatment. The Danish Medicines Council's evaluations were similar in both cases, concluding that the value of the treatment, taking uncertainty into account, did not match the cost of the treatments, when compared with the current best available treatment. For this reason, the Danish Medicines Council did not recommend the two CAR-T treatments as standard treatment in Danish public hospitals. This has led pharmaceutical companies to focus on new and innovative market access strategies to be able to offer this type of treatments in Denmark. The two cases emphasize the challenge of gaining market access with novel treatments through the course of seeking recommendation as standard treatment.



Bristol Myers Squibb

Bristol Myers Squibb is thrilled to be the case company of PCC Impact 2021. We chose to partner with Polit Case Competition to gain high-quality inputs from top-tier economics students on an area at the forefront of the pharmaceutical industry. I am beyond excited to see what this case competition brings. I thank you in advance for your engagement.

- **Anders Thelborg,**
General Manager at Bristol Myers Squibb Denmark



We are proud to present this year's case company, which is one of the largest pharmaceutical companies in the world, Bristol Myers Squibb. Headquartered in the US, Bristol Myers Squibb is a Fortune 500 global biopharmaceutical company dedicated to discovering, developing and delivering innovative medicines that help patients prevail over serious diseases. With more than 30,000 employees, Bristol Myers Squibb operates with the vision of being the world's leading biopharmaceutical company that transforms patients' lives through science. Bristol Myers Squibb delivers medicines in a broad range of disease areas including oncology, hematology, immunology, and cardiovascular diseases.

2020 HIGHLIGHTS

$42.5b
Worldwide revenues

30.000+
Global Workforce

13
approvals for new medicines

Bristol Myers Squibb presents Vixtocar

Through large investments in research and development, Bristol Myers Squibb has succeeded in developing a form of revolutionary cell therapy to treat Brown's lymphoma. The treatment, Vixtocar, is based on CAR-T technology and shows extraordinarily positive effects in clinical studies. For this reason, Vixtocar has obtained very early approval for medical use. Yet, the success of this great effort lies in making Vixtocar available to patients. Vixtocar is currently approved by the European Medicines Agency (EMA) and the Danish Medicines Agency as a third-line treatment, meaning that Bristol Myers Squibb can market the treatment to patients in Denmark who are not cured after two rounds of conventional treatment. However, Bristol Myers Squibb has not yet decided on market access and pricing strategies that ensure the availability for patients and profitability for Bristol Myers Squibb in Denmark. This will be your task in this year's Impact case in Polit Case Competition.

LEGAL NOTICE

To an extent that is greater than ever before, this year's case competition outlines a genuine problem for the case company, and your input may in turn have an actual impact on Danish patients. However, due to the extensive regulation of medical products in Denmark and the EU regarding – among others – pre-marketing practices, Bristol Myers Squibb is unable to disclose detailed information about an upcoming product. Therefore, we refer to the cancer form in question by the fictional name Brown's lymphoma throughout this case.

The Case Questions

This year's case competition asks you to propose a strategy that either ensures Vixtocar as standard treatment in Danish hospitals or allows the treatment to enter the Danish market in alternative ways. For Bristol Myers Squibb Denmark, maximizing revenue and profits is equivalent. Therefore, your mandate is to:

Design a revenue-maximizing market access strategy for Vixtocar in Denmark, based on a sound health technology assessment

The case is divided into three parts

1. **Do the math *(suggested time allocation: 30%)***

Calculate the gain in Quality-Adjusted Life Years (QALYs) that you expect Vixtocar to provide when compared to chemotherapy, and formulate the subsequent Incremental Cost-Effectiveness Ratio (ICER)

Elements to consider

- *The QALY calculation should take into account the uncertainty of the effect of the treatment*
- *The ICER will depend on the price charged for the treatment, which you will not decide upon until later*

2. **Choose a direction *(suggested time allocation: 30%)***

Estimate the willingness to pay for Vixtocar of the Danish Medicines Council and decide whether it is optimal for Bristol Myers Squibb to apply for becoming standard treatment in Danish hospitals

Elements to consider

- *The Danish Medicines Council takes the uncertainty regarding treatment effects into account when deciding on their willingness to pay for novel treatments*

3. **Plan and execute *(suggested time allocation: 40%)***

Design a strategy that ensures that Vixtocar becomes standard treatment, or propose an alternative approach to gaining access to the market. Given your proposed strategy, assess the benefits for Bristol Myers Squibb in Denmark.

You will be judged on the entire aspect of your analysis and solution, including the decisions you make along the way, and how you document and argue for them.

Background material

This section provides you with background material that helps you solve this year's case.

Costs and effects of new treatments

In order for a given treatment to be offered at public hospitals in Denmark, the Danish Medicines Council generally needs to recommend the treatment as standard treatment. This recommendation is based on an evaluation of whether the price of the treatment matches the value of the treatment when compared to the current best available alternative. This evaluation is the primary task of the Danish Medicines Council.

To carry out this analysis, the Medicines Council conducts a Health Technology Assessment which guides policymakers on the medical, organizational, economic, and societal consequences of implementing the new treatment. In this context, health technology is broadly defined and covers any intervention or treatment that may be used to promote health, to prevent, diagnose or treat disease, or for rehabilitation or long-term care. The main component of this Health Technology Assessment is cost-effectiveness analysis.

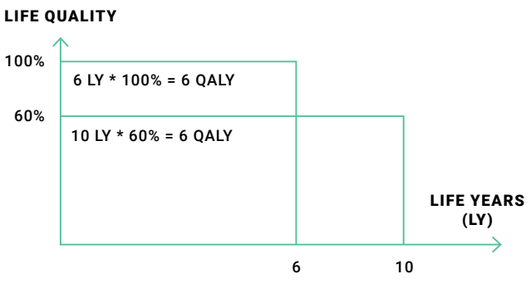
In this year's case, we ask you to conduct such a cost-effectiveness analysis of Vixtocar. Specifically, we ask you to calculate the Quality-Adjusted Life Years (QALYs) and the Incremental Cost-Effectiveness Ratio (ICER) to properly assess the costs and health benefits of Vixtocar, compared to the current best available alternative, which is chemotherapy.

Quality-Adjusted Life Years

When evaluating the effectiveness of a treatment, it is relevant to consider both the additional life years won, as well as the life quality given your health state of the remaining life years. The quality of life is dependent on factors such as age, disease, and disabilities, and is generally not stable at 100% throughout an average life. Quality-Adjusted Life Year (QALY) is a measure that takes this into account and is calculated by weighing remaining life years with the quality of life over these years.

EXAMPLE

If a treatment gives a patient an expected 10 life years with 60% life quality, this corresponds to 6 QALYs. However, 6 QALYs can also be obtained through a treatment that gives 6 life years at a quality of 100%.



Quality of life with Vixtocar

Studies have shown that life quality for patients suffering from Brown's lymphoma is 60% on average after being diagnosed. Due to the adverse effects of chemotherapy, the life quality drops to 55% when treated this way. Since Vixtocar is a one-time treatment, life quality increases to 80% when treated this way. Assume that the health state values are constant over the remainder of the patient's life.

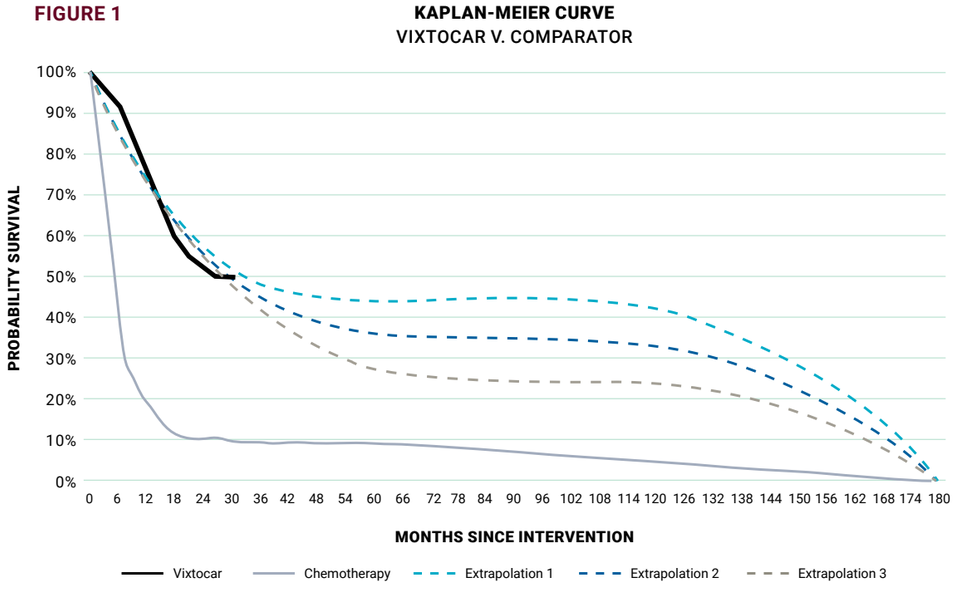
Life expectancy with Vixtocar

Based on Bristol Myers Squibb's clinical studies, Figure 1 shows a Kaplan-Meier curve - also known as the survival rate curve - for patients administered Vixtocar and chemotherapy, respectively. As seen from the graph, the probability of a patient, treated with chemotherapy, being alive after 12 months is 20%. In comparison, the probability of a patient, treated with Vixtocar, being alive after 12 months is 74%. The clinical studies thus indicate that Vixtocar is substantially more effective in treating Brown's lymphoma than chemotherapy when given as treatment in the third line.

Due to Vixtocar's short time-horizon of existence, the clinical trials are not very comprehensive. At this point in time, patients have not been followed for longer than 30 months, which gives rise to a large degree of uncertainty when evaluating the long-term effects of Vixtocar. For this reason, the survival rate curve, from this point forward, is based on extrapolations. Figure 1 shows the three different extrapolations, all based on the clinical study data, which are deemed most likely by researchers. However, as of today, we do not know which extrapolation will turn out to be the correct one – only time will tell. Each extrapolation gives rise to a particular interpretation of the long-term effects of Vixtocar, which is illustrative of the large degree of uncertainty. We ask you to consider this uncertainty when calculating the amount of QALYs gained.

Since patients with Brown's lymphoma are generally relatively old, the survival rate drops to zero within a time-frame of 15 years for all patients, since natural occurrences will lead to deaths, even if the patient is cured of Brown's lymphoma.

FIGURE 1



NOTE: The curves for Vixtocar and Chemotherapy are based on available data from clinical trials. The extrapolations are made on the basis of the available data from clinical trials on Vixtocar, showing the most likely developments of the Vixtocar-curve after month 30 i.e. where we do not have clinical data yet.

Calculating **Incremental Cost-Effectiveness Ratio**

Incremental Cost-Effectiveness Ratio (ICER) is an intuitive tool used to assess the value of a new treatment solution. The measure scales the difference in cost between the new treatment and the comparator by the difference in QALYs gained. Therefore, the ICER can be interpreted as the cost paid for obtaining one additional QALY when adopting the new treatment regime. For the treatment of Brown's lymphoma, the comparator is the current treatment, chemotherapy.

$$ICER = \frac{\Delta Cost}{\Delta QALY} = \frac{Cost\ of\ new\ treatment - cost\ of\ existing\ treatment}{QALY\ of\ new\ treatment - QALY\ of\ existing\ treatment}$$

The cost of both the new treatment and the comparator is based on a health economic assessment that entails all costs directly related to the treatment. This includes the price of the treatment, all related hospitalization costs, and the time value for patients and relatives, for example. Productivity benefits or losses, transfer payments, and other socioeconomic costs should not be included when assessing the cost of treatment. All of the costs are summarized in Table 1.

TABLE 1

(DKK)	VIXTOCAR	*CHEMOTHERAPY*	*INCREMENTAL COSTS*
Price of treatment	*To be decided as part of market access strategy*	*100.000*	*- 100.000 + price of Vixtocar*
Hospital costs	*850.000*	*200.000*	*650.000*
All other costs	*100.000*	*150.000*	*- 50.000*
Total costs	*950.000 + price of Vixtocar*	*450.000*	*500.000 + price of Vixtocar*

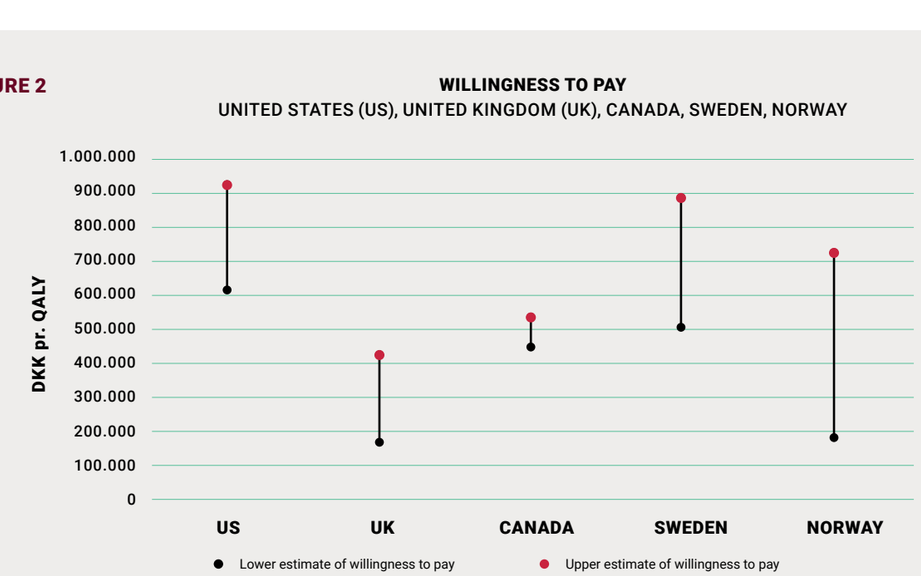
Willingness to pay of the Danish Medicines Council

When the Danish Medicines Council assesses whether a new treatment should be recommended as standard treatment at public Danish hospitals, they compare the ICER of the novel technique with their willingness to pay for one additional QALY. If the willingness to pay exceeds the ICER, the treatment is generally recommended as standard treatment. This assessment principle based on QALY and ICER was adopted by the Danish Medicines Council in early 2021.

The willingness to pay is generally not known and depends on a number of factors, including the severity of the disease in question, the certainty of health effects, societal costs, and the cost of other potential health interventions. Due to the recent adoption of QALY and ICER, no baseline has been established for the Danish Medicines Council's willingness to pay for one additional QALY, which is why you are asked to estimate this. There is no single correct way of doing this.

As a reference, Figure 2 shows estimates of willingness to pay in a range of other countries, based on empirical studies, but note that substantial differences between the healthcare systems exist.

FIGURE 2



CASE STUDIES: TWO CAR-T TREATMENTS REJECTED AS STANDARD TREATMENT

In 2019, the Danish Medicines Council rejected two CAR-T type treatments, Kymriah and Yescarta, as standard treatment for a similar, but different type of lymphoma. Both treatments had technology and effects similar to the benefits of Vixtocar. Based on the list prices, the total costs of Kymriah exceeded chemotherapy by DKK 2.600.000, while Yescarta exceeded chemotherapy by DKK 3.050.000. The size of a potential rebate, negotiated by Amgros, was unknown. In both cases, the Danish Medicines Council noted that the price was very high, but they also emphasized that the high uncertainty regarding the treatment effect played a large role in the rejection.

Ensuring standard treatment recommendation by **matching cost-effectiveness and willingness to pay**

National health authorities – including the Danish Medicines Council – have increasingly started welcoming innovative pricing schemes and trade agreements with the aim of enabling the trade of a treatment that would otherwise be deemed too expensive. These agreements could include, but are not limited to, rebates and discounts given by the pharmaceutical company, price-volume agreements, dynamic price setting, risk-sharing agreements, and/or performance-based agreements. In the two latter, the healthcare payer and the pharmaceutical company share the risks associated with the uncertainty of clinical outcomes of patients treated with the innovative treatment. In other words, the healthcare payer partly or fully conditions the payment on the outcome of the treatment for each patient.

Alternative market access strategies are gaining popularity

With the rise of the novel and costly, but potentially very beneficial treatments, alternative approaches to obtaining market access are becoming increasingly relevant. This is because, in some cases – given the uncertainty – securing recommendation as standard treatment may imply that prices must fall so low that this option is suboptimal for the pharmaceutical company. If this is the case, the company is faced with the question of whether any other option will maximize their revenue in Denmark.

Traditionally, the most applied solution to this problem has been to withdraw the application for standard treatment, and perhaps conduct further research to better document the effects of the treatment. However, since Vixtocar is approved by the European Medicines Agency (EMA) and the Danish Medicines Agency, a testament to the safety of the treatment, the treatment could potentially be offered outside public health service (e.g. in private hospitals) where the costs of the treatment are not borne by the public.

Pharmaceutical companies have recently started paying more attention to these alternative approaches to gaining market access. The solutions already explored in individual cases include, but are not limited to, the initiative to go to the private market, facilitated by private hospitals and health clinics, entering into agreements with health insurance providers, partnering with research institutes, or exerting political pressure.

CASE STUDY: LUXTURNA - A PERFORMANCE-BASED, RISK-SHARING MANAGED ENTRY AGREEMENT

In 2019, Novartis, a global pharmaceutical company, applied for a standard-treatment recommendation from the Danish Medicines Council of an innovative gene therapy treatment, Luxturna, which treats a rare eye disease that eventually leads to blindness. Initially, the Danish Medicines Council decided not to recommend the use of Luxturna as standard treatment based on the assessment that the price of the treatment did not match the clinical value, given the uncertainty about the long-term effects.

However, in 2020, Luxturna was ultimately recommended as a standard treatment by the Danish Medicines Council based on a reapplication filed by Novartis. In the reapplication, Novartis proposed an innovative performance-based, risk-sharing market access agreement, a so-called "no-cure, no-pay" agreement, effectively transferring risk and uncertainty from the Danish Medicines Council to Novartis. In this specific no-cure, no-pay model, the Danish regions will split the payment up in a number of rates, instead of all at once, and regions only pay if the treatment has the desired effect. If it turns out that the treatment does not have the desired effect, regions do not have to pay the subsequent rates.

CASE STUDY: ZYNTEGLO - AN EFFORT TO JOINTLY PROCURE NEW HIGH-COST TREATMENTS

In 2015, the Nordic Pharmaceutical Forum was established with the aim of joining forces and pooling buying and negotiation powers of healthcare providers in the Nordics. Currently, representatives from Iceland, Norway, Sweden, and Denmark are taking part in the Forum. By negotiating jointly, the countries hope to achieve acceptable prices for new high-cost treatments, and thereby ensure rapid and equal access to the treatment for patients in all the Nordic countries. In addition, the Forum wants to make it more attractive for pharmaceutical companies to supply medicines to the Nordic countries that – in a global context – are only small markets.

In 2020, an American biotechnology company, Bluebird Bio, was invited into the Nordic Pharmaceutical Forum for joint negotiations on its high-cost gene therapy Zynteglo, which treats a rare form of genetic blood disorder. The plan with the joint negotiations was to construct treatment centers in one or two of the Nordic countries in order to lower administrative costs and service patients from all of the Nordic countries. Bluebird Bio is the first pharmaceutical company being invited to joint negotiations within the Nordic Pharmaceutical Forum, and the results are pending.

Additional material

This section provides you with additional material to help you solve this year's case.

Characteristics of **the patient base**

Brown's lymphoma can develop from early adulthood, but the likelihood increases with age. For the same reason, Brown's lymphoma is primarily diagnosed in older patients, with a median age at diagnosis of 67 years. Brown's lymphoma is slightly more common among men, who constitute 56% of the diagnosed patients.

It is estimated that approximately 500 patients are diagnosed with Brown's lymphoma in Denmark yearly. 20% experience relapse or refractory Brown's lymphoma after two lines of systemic therapy, qualifying them for third-line treatment. Of these patients at third-line treatment, it is estimated that between 25% and 50% will be candidates for Vixtocar.

In the Nordics, approximately 2.100 patients are diagnosed with Brown's lymphoma yearly, while the number is approximately 400.000 globally.

Treating **Brown's lymphoma**

At public hospitals, the treatment of Brown's lymphoma is carried out in standard treatment lines, where each treatment line represents the order of the given treatment i.e. if treatment is given as a standard first-line treatment, it is the first treatment that patients suffering from Brown's lymphoma are given. Today, the recommended first- and second-line treatment for Brown's lymphoma is chemotherapy, which is given in either combination with other medicine or with stem-cell transplants. If these two rounds of conventional treatment fail, there is currently no recommended third-line treatment of Brown's lymphoma. However, in practice, patients who are not cured after two rounds of conventional treatment, are currently offered additional chemotherapy. Therefore, chemotherapy, given in the third line, is the relevant comparator for Vixtocar.

Becoming **standard treatment** at public Danish hospitals

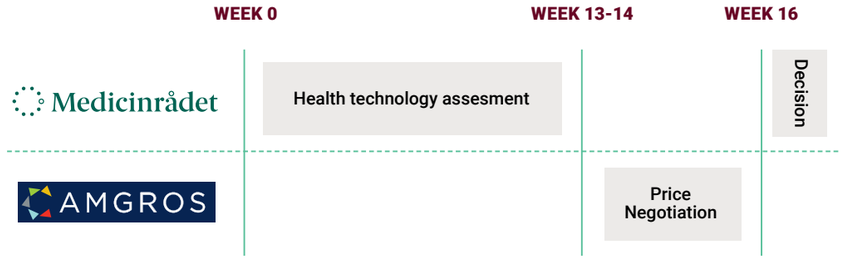
Once a drug is deemed medically safe and approved by either the European Medicines Agency (EMA) or the Danish Medicines Agency, most companies choose to enter the Danish market by applying for the drug to become standard treatment at Danish hospitals, as the private market for therapeutic treatment is quite small. In practice, becoming standard treatment means that the particular drug will become the go-to treatment at public hospitals.

The process of becoming standard treatment goes through the Danish Medicines Council ("Medicinrådet") that assesses the costs and benefits of treatments, and based on this recommends which treatments give the most value for money in the public health system.

The Danish Medicines Council operates with standard treatments at different lines for a given disease. If treatment is recommended as standard treatment in line 1, it is the first treatment offered to the patient. If this treatment fails, i.e. if the patient experiences relapse or refractory of the disease, the second-line treatment is used, and so on. Naturally, treatments in the first line are used more often than in the third line, for example.

When a pharmaceutical company applies for becoming standard treatment, the Danish Medicines Council prepares an assessment report of the effectiveness and benefits, measured by QALY and the subsequent ICER. Based on this assessment, Amgros and the company enter a price negotiation, settling on a price and payment structure for the treatment. Amgros communicates this to the Danish Medicines Council, who update their assessment report and ultimately recommends whether the new treatment can be recommended as standard treatment. The process takes 16 weeks in total.

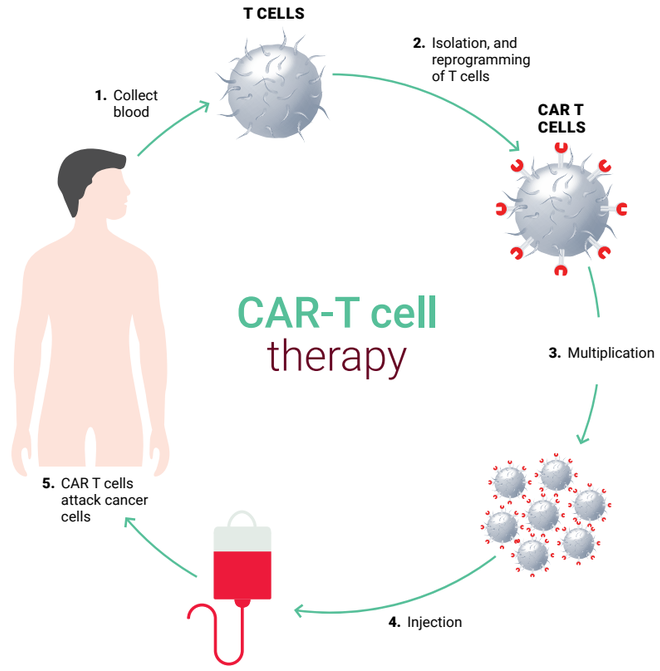
FIGURE 3: Timeline of reimbursement process



Amgros is the public agency with the task of ensuring the supplies of medicines to Danish hospitals procured at the best possible prices. For this reason, the negotiation process is anchored in Amgros, a separate entity from the Danish Medicines Council ("Medicinrådet"), although the two entities work together rather closely.

What is **CAR-T treatment?**

Chimeric Antigen Receptor T-cell therapy (CAR-T) is a promising new form of immunotherapy, where immune cells, specifically T-cells (a type of white blood cells), are taken out of the patient, modified in a laboratory to specifically fight cancer cells, and ultimately injected back into the patient to effectively find and destroy cancer cells.



CAR-T Treatment: Step by step

Step 1: The CAR-T therapy starts by removing white blood cells, which include T-cells, from the patient. The T-cells are separated and sent to a laboratory.

Step 2: In the laboratory, the T-cells are genetically altered by adding the specific chimeric antigen receptor (CAR). This makes them CAR-T cells.

Step 3: CAR-T cells are duplicated until the correct dose of the treatment is obtained. It can take a few weeks to make the large number of CAR-T cells needed for the therapy.

Step 4: The CAR-T cells are injected back into the patient to effectively find and destroy cancer cells. A few days before a CAR-T cell infusion, the patient might be given immunosuppressive medicine to lower the number of other immune cells. This gives the CAR-T cells a better chance to fight the cancer cells.

Step 5: The CAR-T cells attack the cancer cells. The CAR-T cells will start binding with cancer cells, which will make them increase in number and destroy even more cancer cells.

Rules and regulations

1. In Polit Case Competition 2021, you are judged solely by the panels of the semi-finale and finale judges, based on your oral presentation, your supporting slide deck, and the subsequent Q&A session. You will be judged on the entire aspect of your analysis and solution, including the decisions you make along the way, and how you document and argue for them.

2. You must submit your slide deck as a single PDF file in 16:9 format at impact2021.innoflow.io no later than 6:30 pm. Late submissions will not be considered.

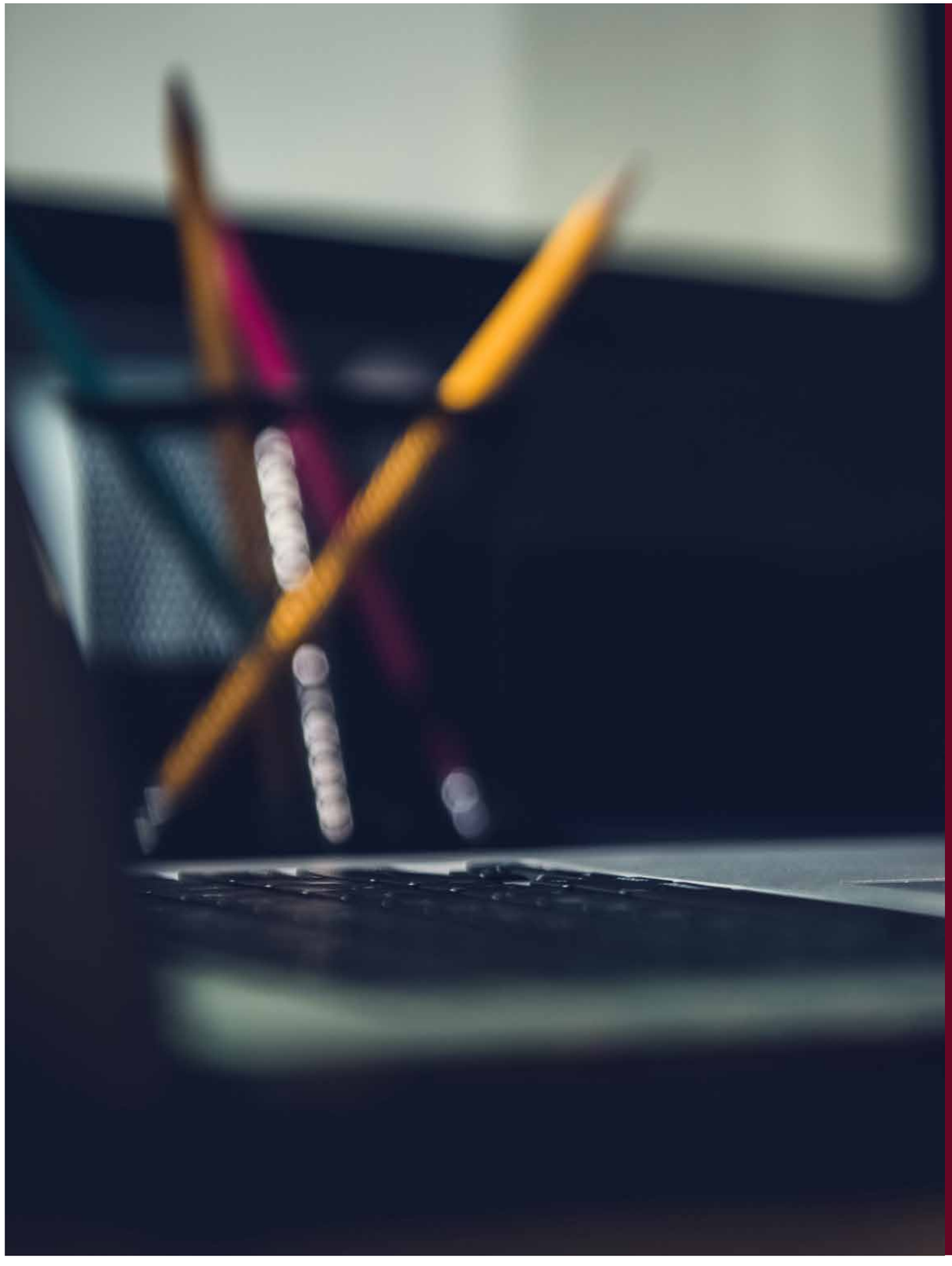
3. Your presentation slide deck must not contain more than 10 slides, including the frontpage. Any supporting documents are not required, nor considered.

4. All content presented must be the original work of the group. In addition to the case information and expert interviews, all publicly available information may be used. Between 10 am and 6:30 pm, no outside aid or communication with other teams is permitted.

5. The oral presentation must not last longer than 8 minutes.

6. In case of organizational questions, these should be addressed to a member of the Polit Case Competition staff in person or by e-mail to info@politcasecompetition.com. We cannot provide input to the case contents.

7. The case must be solved on the premises provided as part of Polit Case Competition 2021.



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