The big leap in immunotherapy has finally arrived in Belgium: Opdivo is now reimbursed for four different types of cancer

Immunotherapy is confirmed as a key new and effective treatment, available to fight cancer beside chemotherapy, surgery or radiotherapy. This is reflected in the increasing number of cancer types that are approved, firmly establishing immunotherapy as future standard of care.

Brussels, 17 January 2017 – So far, cancer treatment with Opdivo in Belgium was only reimbursed for advanced melanoma since April 2016. It was a milestone in the fight against cancer, but only a precursor compared to the true revolution immunotherapy has gone through now: three other types of cancer are added to the list of reimbursement for Opdivo (advanced or metastatic non-small cell lung cancer, advanced renal cell carcinoma and relapsed or refractory classical Hodgkin lymphoma after autologous stem cell transplant and treatment with brentuximab vedotin). Furthermore, the treatment of advanced melanoma has also been approved for reimbursement for a combination therapy with Opdivo and Yervoy; which is now the first and only approved combination of immune checkpoint inhibitors in advanced melanoma. The announcement of these reimbursements itself is also undoubtedly an unprecedented leap forward: never before has there been a parallel approval of multiple indications and the accelerated speed of these approvals compared to the standard process is unheard- of. On top of that, an agreement signed with the Belgian authorities secures the reimbursement of all future indications of Opdivo on the first day of the month following the European Commission's approval. This, of course, is great news for the patients, as immunotherapies are brought to them at a much faster pace.

Locally advanced or metastatic Non-Small Cell Lung Cancer

One of 4 cancer types for which Opdivo will now be reimbursed is locally advanced or metastatic non-small cell lung cancer (NSCLC). As NSCLC accounts for about 85% of all lung cancers, needless to say this is ground-breaking news considering lung cancer remains one of the most common types of cancer. In this population of NSCLC patients, Opdivo improved long term survival up to three times when compared to standard chemotherapy, depending on the histology of the tumor. "*With the approval of Opdivo for treatment of locally advanced or metastatic non-small cell lung cancer, patients will now have a very good alternative compared to the standard treatments*", explains professor Johan Vansteenkiste, Respiratory Oncologist at the Leuven University Hospital. "*The results obtained in clinical trials with Opdivo for patients with NSCLC are no less than impressive. Previously treated NSCLC patients who were treated with Opdivo showed an improvement in overall survival. Moreover, the responses seen with Opdivo were more durable when compared to docetaxel, a type of chemotherapy, and the safety profile was more favourable as well – leading to an overall improvement in quality of life for the patients".*

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Advanced Renal Cell Carcinoma

With 100.000 deaths worldwide each year, renal cell carcinoma (RCC) is the most common type of kidney cancer. In diagnosis of RCC, up to 30% of cases are already in a metastatic or advanced stage. So evidently, the reimbursement of Opdivo for treatment of advanced RCC in Belgium is yet another milestone in the fight against this cancer. Professor Jean-Pascal Machiels, Medical Oncologist at the King Albert II Institute Brussels, clarifies the research results of Opdivo as an RCC treatment: "*The research results Opdivo showed in previously treated advanced RCC patients are a major breakthrough compared to everolimus, the standard treatment: the relative risk of dying was reduced by 27%. In addition, the response rate was 5 times better than the response rate of the standard treatment. Half of the patients were still alive at 26 months, compared to 19 months for everolimus. These are unprecedented results*".

Relapsed or refractory classical Hodgkin lymphoma after autologous stem cell transplant and treatment with brentuximab vedotin

Relapsed or refractory classical Hodgkin lymphoma, after autologous stem cell transplant and treatment with brentuximab vedotin, is the third new type of cancer that is added to Belgium's reimbursement list for Opdivo. Classical Hodgkin lymphoma makes up about 95% of all Hodgkin lymphoma incidences, so once again the reimbursement is great news for the patients. This is the first and only immunotherapy for Hodgkin lymphoma to be approved for reimbursement in Belgium. Which is an amazing evolution, because the patients who were previously treated and relapsing from those heavy treatments – such as chemotherapy, radiotherapy and transplants – now have a new treatment option, which allows them to be optimistic once again. The results of research were very promising: patients treated with Opdivo showed impressive response rates and durability of response. The objective response rate was 68% at 12 months and the progression-free survival was prolonged with no less than 5 months with extended follow-up. Especially considering the fact that these patients with relapsed or refractory classical Hodgkin lymphoma are a very difficult-to-treat population, these results are very auspicious.

Advanced melanoma

The reimbursement of Opdivo for advanced melanoma in Belgium has already been approved for some months. Melanoma was actually the first type of cancer in which immunotherapy research showed great results, with a long-term survival benefit in treatment with Yervoy, for patients whose prognosis was otherwise extremely poor. But now, for the first time, a combination of two different immunotherapies will be reimbursed for advanced melanoma: the combination therapy of Opdivo (nivolumab) and Yervoy (ipilimumab). Research indicated that the complementary mechanism of action of both immunotherapies results in superior anti-tumor efficacy than either agent alone. The results showed a longer median progression-free survival of 11,5 months with a higher and durable objective response rate of 58% for the combination of both Opdivo and Yervoy as first-line treatment of advanced melanoma, as compared relatively to Opdivo alone, which showed a median progression-free survival of 6.9 months and an objective response rate of 44%.

BMS, a key partner in immuno-oncology

Scott Cooke, General Manager Benelux of Bristol-Myers Squibb, comments: "*It is a victory, not just for us, but for the whole medical world and – most importantly – for the patients. Immunotherapy had its first breakthrough when the political field decided to reimburse treatment of advanced melanoma, but that breakthrough was only a first victory compared to this. Not only is this the first time multiple indications are approved for reimbursement at the same time in Belgium, it also happened at a much faster pace. And on top of that, all future indications will be reimbursed starting from the first day of the month following the European Commission's approval. At Bristol-Myers Squibb, we are very proud to be the first company to ever achieve this, because it shows our dedication and responsibility towards the patients. It is the true start of the immunotherapy era. The approval of Opdivo in four different types of cancer, as well as the approval of a combination therapy with Yervoy for advanced melanoma, means one thing above all: hope. It is a new hope for all these different types of patients who can potentially benefit from the great results of immunotherapy. This revolutionary new method of treatment has now become a real medical alternative to the traditional treatments, chemotherapy and radiotherapy. We believe it will continue to gain importance in the coming years, gradually becoming the standard treatment.*"

About Bristol-Myers Squibb

Bristol-Myers Squibb Belgium is an indirect subsidiary fully owned by the Bristol-Myers Squibb Company, a global biopharmaceutical company with a mission: discovering, developing and delivering innovative medicine, in order to help patients in the fight against serious diseases. For more information, visit our website www.bms.be.

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