AstraZeneca and Merck Establish Strategic Oncology Collaboration

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Collaboration Aims to Maximize the Potential of PARP and MEK Inhibitors in Combination with PD-L1/PD-1 Medicines, Based on Growing Scientific Evidence That These Combinations Offer New Potential for the Treatment of a Range of Tumor Types

AstraZeneca and Merck Will Independently Develop and Commercialize LYNPARZA and Potential Medicine Selumetinib in Combinations with Companies’ Respective PD-L1/PD-1 Immuno-Oncology Medicines IMFINZI and KEYTRUDA

Collaboration Will Significantly Expand the Potential of LYNPARZA, the World’s First and Leading PARP Inhibitor, as a Monotherapy and as a Backbone of Combination Treatments for Multiple Cancer Types; Agreement Also Includes AstraZeneca’s Selumetinib, a MEK inhibitor

The Companies Will Share Development and Marketing Costs Equally, as well as Gross Profits from LYNPARZA and Selumetinib

KENILWORTH, N.J.--(BUSINESS WIRE)--AstraZeneca and Merck & Co., Inc., (NYSE: MRK), known as MSD outside of the United States and Canada, today announced that they have entered a global strategic oncology collaboration to co-develop and co-commercialize AstraZeneca’s LYNPARZA (olaparib) for multiple cancer types. LYNPARZA is an innovative, first-in-class oral poly ADP ribose polymerase (PARP) inhibitor currently approved for BRCA-mutated ovarian cancer in multiple lines of treatment.

LYNPARZA’s pipeline has grown significantly in the last few years, with 14 indications currently being developed across several tumor types, including breast, prostate and pancreatic cancers. The strategic collaboration is expected to further increase the number of treatment options available to patients.

The companies will develop and commercialize LYNPARZA jointly, both as monotherapy and in combination trials with other potential medicines. Independently, the companies will develop and commercialize LYNPARZA in combinations with their respective PD-L1 and PD-1 medicines, IMFINZI (durvalumab) and KEYTRUDA (pembrolizumab).

The companies will also jointly develop and commercialize AstraZeneca’s selumetinib, an oral, potent, selective inhibitor of MEK, part of the mitogen-activated protein kinase (MAPK) pathway, currently being developed for multiple indications including thyroid cancer.

Pascal Soriot, chief executive officer of AstraZeneca, said: “Our strategic collaboration builds on scientific evidence that PARP and MEK inhibitors can be combined with PD-L1/PD-1 inhibitors for a range of tumors. By bringing together the expertise of two leading oncology innovators, we will accelerate LYNPARZA’s potential to become the preferred backbone of many immuno-oncology combination therapies as the world’s first and leading PARP inhibitor. This is a truly exciting step and we
are pleased to work with Merck, a company that shares our passion for science to deliver new medicines for cancer patients."

Kenneth C. Frazier, chief executive officer of Merck, said: “This global collaboration between AstraZeneca and Merck, two oncology leaders, will increase the possibilities for patients to have more treatment options for more cancers. Merck continues to build its leadership in immuno-oncology with KEYTRUDA as foundational in monotherapy and combination therapy, and this collaboration expands our oncology leadership into the growing targeted therapies of PARP and MEK inhibitors. We look forward to working with AstraZeneca to create greater value for patients and shareholders than if both companies worked independently.”

**Financial considerations**

Under the terms of the agreement, AstraZeneca and Merck will share the development and commercialization costs for LYNPARZA and selumetinib monotherapy and non-PD-L1/PD-1 combination therapy opportunities. Gross profits from LYNPARZA and selumetinib product sales generated through monotherapies or combination therapies will be shared equally.

Merck will fund all development and commercialization costs of KEYTRUDA in combination with LYNPARZA or selumetinib. AstraZeneca will fund all development and commercialization costs of IMFINZI in combination with LYNPARZA or selumetinib.

AstraZeneca will continue to manufacture LYNPARZA and selumetinib.

As part of the agreement, Merck will pay AstraZeneca up to $8.5 billion in total consideration, including $1.6 billion upfront, $750 million for certain license options and up to an additional $6.15 billion contingent upon successful achievements in future regulatory sales milestones.

Merck expects to book its share of product sales of LYNPARZA and selumetinib, net of commercialization costs, as Alliance Revenue and its share of development costs associated with the collaboration as part of its Research & Development expense.

The collaboration agreement was completed upon signing on July 26, 2017.

**About LYNPARZA**

LYNPARZA (olaparib) is an innovative, first-in-class oral poly ADP-ribose polymerase (PARP) inhibitor that may exploit tumour DDR pathway deficiencies to preferentially kill cancer cells. LYNPARZA is the foundation of AstraZeneca’s industry-leading portfolio of potential new medicines that target DDR mechanisms in cancer cells. LYNPARZA is currently approved by regulatory health authorities in the EU for use as monotherapy for the maintenance treatment of adult patients with platinum-sensitive, relapsed BRCA-mutated (germline and/or somatic), high-grade serous epithelial ovarian, fallopian tube or primary peritoneal cancer, who are in response (complete or partial) to platinum-based chemotherapy. It is also approved in the US as a monotherapy for patients with deleterious, or suspected deleterious, germline BRCA-mutated (as detected by a US FDA test) advanced ovarian cancer, who have been treated with three or more lines of chemotherapy.

The company recently presented positive results for LYNPARZA from its Phase III OlympiAD trial that showed a statistically-significant and clinically-meaningful improvement in progression-free survival for patients treated with LYNPARZA tablets (300 mg twice daily), compared to treatment with physician’s choice of a standard of care chemotherapy. OlympiAD, a randomised, open-label, multi-centre Phase III trial assessing the efficacy and safety of LYNPARZA in patients with HER2-negative metastatic breast cancer with germline BRCA1 or BRCA2 mutations, which are predicted or suspected to be deleterious, was the first positivePhase III trial to evaluate the efficacy and safety of PARP inhibitor beyond ovarian cancer. LYNPARZA is currently being investigated in another separate non-metastatic breast cancer Phase III trial called OLYMPIA. This trial is still open and recruiting patients internationally.

LYNPARZA generated Product Sales in 2016 of $218 million.

**About Selumetinib**

Selumetinib, licensed by AstraZeneca from Array BioPharma Inc. in 2003, inhibits the MEK enzyme in the RAS/RAF/MEK/ERK pathway in cancer cells to prevent the tumour from growing. Selumetinib is in Phase III development for differentiated thyroid cancer, for which it was granted Orphan Drug Designation by the FDA in May 2016.

Selumetinib is also being tested in a separate Phase II trial in patients with paediatric neurofibromatosis type-1, and in a Phase I trial with patients suffering from advanced solid tumours.

**Merck’s Focus on Cancer**

Our goal is to translate breakthrough science into innovative oncology medicines to help people with cancer worldwide. At Merck, helping people fight cancer is our passion and supporting accessibility to our cancer medicines is our commitment. Our focus is on pursuing research in immuno-oncology and we are accelerating every step in the journey – from lab to clinic – to potentially bring new hope to people with cancer.

As part of our focus on cancer, Merck is committed to exploring the potential of immuno-oncology with one of the fastest-growing development programs in the industry. We are currently executing an expansive research program that includes more than 500 clinical trials evaluating our anti-PD-1 therapy across more than 30 tumor types. We also continue to strengthen our immuno-oncology portfolio through strategic acquisitions and are prioritizing the development of several promising immunotherapeutic candidates with the potential to improve the treatment of advanced cancers.

For more information about our oncology clinical trials, visit [www.merck.com/clinicaltrials](http://www.merck.com/clinicaltrials).

**About Merck**

For more than a century, Merck, a leading global biopharmaceutical company known as MSD outside of the United States and Canada, has been inventing for life, bringing forward medicines and vaccines for many of the world’s most challenging diseases. Through our prescription medicines, vaccines, biologic therapies and animal health products, we work with customers and operate in more than 140 countries to deliver innovative health solutions. We also demonstrate our commitment to increasing access to health care through far-reaching policies, programs and partnerships. Today, Merck
continues to be at the forefront of research to advance the prevention and treatment of diseases that threaten people and communities around the world - including cancer, cardio-metabolic diseases, emerging animal diseases, Alzheimer's disease and infectious diseases including HIV and Ebola. For more information, visit www.merck.com and connect with us on Twitter, Facebook, Instagram, YouTube and LinkedIn.

**Forward-Looking Statement of Merck & Co., Inc., Kenilworth, N.J., USA**

This news release of Merck & Co., Inc., Kenilworth, N.J., USA (the “company”) includes “forward-looking statements” within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. These statements are based upon the current beliefs and expectations of the company’s management and are subject to significant risks and uncertainties. There can be no guarantees with respect to pipeline products that the products will receive the necessary regulatory approvals or that they will prove to be commercially successful. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements.

Risks and uncertainties include but are not limited to, general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; global trends toward health care cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; the company’s ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; dependence on the effectiveness of the company’s patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions.

The company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in the company’s 2016 Annual Report on Form 10-K and the company’s other filings with the Securities and Exchange Commission (SEC) available at the SEC’s Internet site (www.sec.gov).

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