This announcement contains inside information

The securities proposed to be offered pursuant to the equity placing referred to herein will not be and have not been registered under the US Securities Act of 1933, as amended, and may not be offered or sold in the United States absent registration or an applicable exemption from registration requirements.

28 March 2019 23:30 GMT

AstraZeneca and Daiichi Sankyo enter collaboration for novel *HER2*-targeting antibody-drug conjugate

Companies to accelerate and expand development of trastuzumab deruxtecan across breast and other cancers, with the potential to redefine standard of care

Funding via an equity placement of approximately $3.5bn

Guidance for 2019 Core Earnings Per Share remains unchanged; growing accretion from 2020 to a significant contribution in 2023

AstraZeneca has entered into a global development and commercialisation collaboration agreement with Daiichi Sankyo Company, Limited (Daiichi Sankyo) for trastuzumab deruxtecan (DS-8201), a proprietary antibody-drug conjugate (ADC) and potential new targeted medicine for cancer treatment.

The collaboration is aligned with AstraZeneca's science-led strategy in Oncology, which is based on four key scientific platforms: tumour drivers & resistance, DNA damage response, Immuno-Oncology and ADCs.

Trastuzumab deruxtecan is currently in development for the treatment of multiple *HER2*-expressing cancers, including breast and gastric cancer, and in patients with *HER2*-low expression. In 2017, trastuzumab deruxtecan was granted Breakthrough Therapy Designation by the US FDA for the treatment of patients with *HER2*-positive, locally-advanced or metastatic breast cancer who have been treated with trastuzumab and pertuzumab and have disease progression after trastuzumab emtansine.

A first regulatory submission is scheduled for the second half of 2019 for patients in the advanced or refractory breast cancer setting. Additional development for the treatment of breast, non-small cell lung cancer (NSCLC), gastric and colorectal cancers is ongoing.

The companies will jointly develop and commercialise trastuzumab deruxtecan worldwide, except in Japan where Daiichi Sankyo will maintain exclusive rights. Daiichi Sankyo will be solely responsible for manufacturing and supply.

Pascal Soriot, Chief Executive Officer, said: "We believe that trastuzumab deruxtecan could become a transformative new medicine for the treatment of *HER2*-positive breast and gastric cancers. In addition, it has the potential to redefine breast cancer treatment as the first therapy for*HER2*-low expressing tumours. It also has the potential to treat other *HER2*-mutated or *HER2*-overexpressing cancers, including lung and colorectal cancers. We are proud to be working with Daiichi Sankyo, a long-term collaborator of AstraZeneca in other disease areas."

George Nakayama, Representative Director, Chairman and Chief Executive Officer of Daiichi Sankyo, said: "Trastuzumab deruxtecan is the flagship asset in our oncology pipeline created by our relentless pursuit of science and technology, the most important strengths of our

company. Through the strategic collaboration with AstraZeneca, a company with a wealth of global experience and expertise in oncology, we will combine our respective skill sets to maximise the value of trastuzumab deruxtecan and accelerate the establishment of our global oncology business. By aiming to provide new treatment options across a wide range of cancers as soon as possible, we will maximise our contribution to patients with cancer and their families around the world."

Using Daiichi Sankyo's DXd proprietary ADC technology, trastuzumab deruxtecan has been designed to deliver chemotherapy selectively to cancer cells and reduce systemic exposure, in contrast to conventional chemotherapy delivery. Data from the ongoing first-time-in-human trial shows strong activity in a number of tumour types. In particular, the strength of the overall response rate and durability of response in patients previously treated with trastuzumab emtansine for *HER2*-positive metastatic breast cancer formed the basis for the Breakthrough Therapy Designation.[1]

Financial considerations
Under the terms of the agreement, AstraZeneca will pay Daiichi Sankyo an upfront payment of $1.35bn, half of which is due upon execution, with the remainder payable 12 months later.

Contingent payments of up to $5.55bn include $3.8bn for potential successful achievement of future regulatory and other milestones, as well as $1.75bn for sales-related milestones.

Overall, the transaction will be accounted for as an intangible asset acquisition, recognised initially at the present value of non-contingent consideration, with future milestones capitalised into the intangible asset as they are recognised. AstraZeneca and Daiichi Sankyo will share equally development and commercialisation costs as well as profits from trastuzumab deruxtecan worldwide, except for Japan.

Daiichi Sankyo will record sales in the US, certain countries in Europe and certain other markets where Daiichi Sankyo has affiliates. Further to the financial reporting announcement below, profits shared with AstraZeneca will be accounted for as Collaboration Revenue by AstraZeneca (see further below, 'Financial reporting presentation').

AstraZeneca is expected to record Product Sales in all other markets worldwide for which profits shared with Daiichi Sankyo will be accounted for as cost of goods sold.

The transaction is expected to be neutral to core earnings in 2019, with growing Core EPS accretion from 2020 and making a significant contribution in 2023. There are no closing conditions to the transaction. The collaboration agreement will become effective on 29 March 2019. The transaction and funding arrangements do not impact the Company's financial guidance for 2019 as published on 14 February 2019.

The upfront payment and near-term milestones under the transaction will be funded from the proceeds of a new equity placement of approximately $3.5bn, of which more than half will be used to fund this transaction and the ongoing collaboration. A separate announcement will be issued by the Company today on the equity placement.

For the purposes of the UK Listing Authority's Listing Rule LR 10.4.1 R (Notification of class 2 transactions), the value of gross assets acquired with the transaction is estimated to be $1.5bn and, in view of the development phase of the medicine, a pre-tax loss of $38m was attributable to trastuzumab deruxtecan during the year to 31 March 2018.

About Trastuzumab deruxtecan

Trastuzumab deruxtecan (DS-8201; [fam-] trastuzumab deruxtecan in US only) is the lead potential new medicine in the ADC franchise of the Daiichi Sankyo Cancer Enterprise. ADCs are targeted cancer medicines that deliver cytotoxic agents to cancer cells via a linker attached to a monoclonal antibody that binds to a specific target expressed on cancer cells.

A broad and comprehensive development programme with trastuzumab deruxtecan is underway in North America, Europe and Asia, including five pivotal trials in *HER2*-expressing breast and gastric cancers. Trastuzumab deruxtecan is also in Phase II development for *HER2*-expressing advanced colorectal cancer and metastatic non-squamous *HER2*-overexpressing or *HER2*-mutated NSCLC, and Phase I development in combination with nivolumab for *HER2*-expressing metastatic breast and bladder cancers.

Trastuzumab deruxtecan was granted Breakthrough Therapy Designation in 2017 by the US FDA for the treatment of patients with *HER2*-positive, locally-advanced or metastatic breast cancer who have been treated with trastuzumab and pertuzumab and have disease progression after trastuzumab emtansine. Fast Track Designation was also granted in the US for the treatment of *HER2*-positive unresectable and/or metastatic breast cancer in patients who have progressed after prior treatment with *HER2*-targeted medicines, including trastuzumab emtansine. Trastuzumab deruxtecan has received Sakigake designation for the treatment of *HER2*-positive advanced gastric or gastroesophageal junction cancer by the Japan Ministry of Health, Labour and Welfare.

Trastuzumab deruxtecan is a potential new medicine that has not been approved for any indication in any country. Safety and efficacy have not been established.

Financial reporting presentation

As a result of this announcement, AstraZeneca also updates the presentation of Total Revenue within its Statement of Comprehensive Income. This is effective from 1 January 2019 and will be reflected in the Company's Q1 2019 financial results that are intended for publication on 26 April 2019.

In 2015, the Company announced a change to the presentation of Total Revenue within its Statement of Comprehensive Income to include Externalisation Revenue. Today's announcement recognises the growing importance of collaborations to AstraZeneca and will result in income arising from those collaborations being recognised within Total Revenues. The associated costs of collaborations will be recognised in the appropriate expense lines in the Statement of Comprehensive Income.

Historically, Externalisation Revenue only included income arising from transactions involving AstraZeneca's medicines. Such income included upfronts, milestones receipts and royalties, as well as other income from collaborations. The updated category of Collaboration Revenue will also include income of a similar nature arising from transactions where AstraZeneca has acquired an interest in a medicine and entered into an active collaboration with the seller.

No prior year restatement of financial results will be required as a result of this change. The change in accounting presentation does not impact the Company's revenue guidance for 2019.

About AstraZeneca

AstraZeneca is a global, science-led biopharmaceutical company that focuses on the discovery, development and commercialisation of prescription medicines, primarily for the treatment of diseases in three therapy areas - Oncology, Cardiovascular, Renal & Metabolism and Respiratory. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. For more information, please visit astrazeneca.com and follow us on Twitter@AstraZeneca.

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