Press Cutting

Client: Chi-Med

Publication: Scrip

Date: 21 December 2011

AstraZeneca tries to plug development gap with two Asian deals
21 December 2011
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Following on from announcing two major pipeline disappointments yesterday, AstraZeneca has signed development deals with two Asian companies in a bid to bolster its early-stage clinical portfolio.

Chi-Med and AstraZeneca have entered a global deal to co-develop a novel cancer treatment, while Astellas Pharma subsidiary Prosidion has granted AstraZeneca an option to buy a new class of diabetes treatments.

AstraZeneca is facing looming patent losses on blockbusters such as Seroquel (quetiapine fumarate) for schizophrenia and Nexium (esomeprazole magnesium) for gastric disorders. Its cholesterol drug Crestor (rosuvastatin) is also under pressure owing to the arrival of generic Lipitor in the US last month.

The setbacks in depression and oncology earlier this week, alongside pre-tax impairment charges totalling $381.5 million to R&D expense in the fourth quarter of 2011, have not helped the spread of good cheer among AstraZeneca's shareholders (scripintelligence.com, 20 December 2011).

cancer dealThe deal with Chi-Med is for volitinib (HMPL-504), which was developed by its subsidiary Hutchison MediPharma. Volitinib is an inhibitor of the c-Met receptor tyrosine kinase, "a similar compound to Iressa [AstraZeneca's approved epidermal growth factor receptor tyrosine kinase inhibitor]", AstraZeneca told Scrip.

Chi-Med has received $20 million up front and is in line for $120 million in development milestone payments, plus significant commercialisation milestone payments and double digit royalties. Astra Zeneca noted that this was its first co-development deal with a Chinese pharmaceutical company on a novel treatment.

It told Scrip: "Volitinib is about to go into clinical testing in its first study, which will take place in Australia. The indications likely to be pursued initially will be cancers that have a high prevalence in Asian countries, like gastric cancer and non-small cell lung cancer."

In an interview with Scrip in October this year, AstraZeneca's head of personalised healthcare and biomarker support Dr Robert Holland explained how AstraZeneca went through an intense period of evaluation around two years ago to understand why it was struggling to get products to market (scripintelligence.com, 12 October 2011). The company identified patient stratification as one of the key areas that would help turn the tide. Over the past couple of years, the pharma giant has changed the entire profile of its portfolio to reach a point where more than half of the product candidates are being developed alongside a biomarker.

"There is the potential for a patient selection strategy in later stage clinical trials for volitinib," AstraZeneca said today.

diabetesThe deal with Prosidion grants to AstraZeneca an exclusive option to acquire the clinical and preclinical assets, PSN821 and PSN 842 respectively, for type 2 diabetes. Both PSN821 and PSN842 are orally administered G protein-coupled receptor GPR119 agonists, a potential new class of medicines for diabetes.

PSN821 is currently in a Phase IIa trial and PSN842 is about to enter clinical testing.

Under the agreement, AstraZeneca will pay Prosidion an undisclosed, non-refundable option fee. The exercise of the option will be dependent on the successful results of the Phase IIa clinical trial of PSN821 and the evaluation of preclinical work. If it exercises the option, AstraZeneca would acquire the assets from Prosidion and would pay an undisclosed, pre-specified upfront payment and milestones.

AstraZeneca's existing diabetes hopes lie with dapagliflozin (in development with Bristol-Myers Squibb), a sodium glucose co-transporter-2 (SGLT-2) inhibitor that was accepted for review by the FDA in March 2011. However, the agency then requested additional data on the drug and extended the Prescription Drug User Fee Act (PDUFA) date by three months to 28 January 2012 (scripintelligence.com, 27 October 2011).

"With their completely different mechanism of action, these assets [from Astellas] will be a good fit with dapagliflozin," AstraZeneca noted.

Yoshihiko Hatanaka, president and CEO, from Astellas, said: "Astellas has conducted an extensive review of strategic alternatives with regard to Prosidion. We are delighted to have found such an experienced partner for these assets. AstraZeneca has a strong track record in the commercialisation and launch of products in competitive primary care markets. Astellas believes this transaction will also support its strategic goal of maximising value for shareholders by optimising R&D resource allocation in order to effectively manage R&D costs."