Current Agreements

Dealdoc

Evaluation agreement for CS-3150 (esaxerenone (r-INN))

Exelixis
Daiichi Sankyo

Sep 26 2016

Evaluation agreement for CS-3150 (esaxerenone (r-INN))

Companies:	Exelixis Daiichi Sankyo
Announcement date:	Sep 26 2016
Deal value, US$m:	15 : sum of milestone payment

Details

Announcement date:	Sep 26 2016
Industry sectors:	Bigbiotech Biotech
Compound name:	CS-3150
Asset type:	Compound
Therapy areas:	Cardiovascular » Hypertension
Technology types:	Small molecules
Deal components:	Evaluation
Stages of development:	Phase III
Geographic focus:	Asia » Japan

Financials

Deal value, US$m:	15 : sum of milestone payment
Milestones, US$m:	15 : milestone payment

Termsheet

Exelixis, Inc. announced that its partner Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) has initiated a phase 3 pivotal trial to evaluate CS-3150 (esaxerenone (r-INN)), an oral, non-steroidal, selective mineralocorticoid receptor antagonist, as a treatment for essential hypertension in Japanese patients.

As a result of Daiichi Sankyo enrolling the first patient in the program’s phase 3 pivotal trial, Exelixis is eligible for a $15 million milestone payment, which it expects to receive in the fourth quarter of 2016.

CS-3150 (esaxerenone (r-INN)) is an oral, non-steroidal, selective antagonist of the mineralocorticoid receptor (MR), a nuclear hormone receptor implicated in a variety of cardiovascular and metabolic diseases.

Press Release

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Exelixis, Inc. (NASDAQ:EXEL) today announced that its partner Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) has initiated a phase 3 pivotal trial to evaluate CS-3150 (esaxerenone (r-INN)), an oral, non-steroidal, selective mineralocorticoid receptor antagonist, as a treatment for essential hypertension in Japanese patients. As a result of Daiichi Sankyo enrolling the first patient in the program’s phase 3 pivotal trial, Exelixis is eligible for a $15 million milestone payment, which it expects to receive in the fourth quarter of 2016.

“We are pleased to see our partner Daiichi Sankyo continue to advance CS-3150 through clinical development and into a well designed phase 3 pivotal trial in Japanese patients with essential hypertension”

In March 2006, Daiichi Sankyo and Exelixis entered into a research collaboration agreement to discover, develop and commercialize novel therapies targeting the mineralocorticoid receptor. Under the terms of the agreement, Daiichi Sankyo has exclusive global development, manufacturing, and commercialization rights for the compounds. CS-3150 is one of the compounds identified during the research collaboration, and has subsequently been developed by Daiichi Sankyo.

The ESAX-HTN phase 3 pivotal trial is a randomized study of CS-3150 versus eplerenone in Japanese hypertensive patients. The trial will enroll an estimated 930 patients into three treatment arms: 2.5 mg and 5 mg doses of CS-3150, and 50 mg of eplerenone. The eighteen-week trial includes a four week washout period, twelve week study period and two week follow-up period. Among other inclusion criteria, to participate in the trial patients must be classified as hypertensive with systolic blood pressure between 140-180 mmHg, diastolic blood pressure between 90-110 mmHg and a mean 24-hour blood pressure reading greater than 130/80 mmHg. The primary objective is to evaluate the antihypertensive effect and safety of CS-3150 2.5 mg once daily compared to eplerenone; a secondary objective is to evaluate the effectiveness of the 2.5 and 5 mg doses of CS-3150.

In addition to ESAX-HTN, Daiichi Sankyo is sponsoring six smaller phase 3 clinical trials of CS-3150 in specific populations of patients with hypertension, either as monotherapy or in combination with other therapies used to treat the condition. The largest of these trials, Study J302, has been active since March 2016 and is a long-term, open-label study to evaluate the efficacy and safety of CS-3150 in 360 patients with essential hypertension, including forms that cannot be controlled by angiotensin II receptor blockers (ARB) or angiotensin converting enzyme (ACE) inhibitors. Another study in the program, J306, will evaluate the efficacy and safety of CS-3150 as an add-on to ARB or ACE inhibitor therapy in patients with hypertension and type 2 diabetes with albuminuria, a population for whom eplerenone is contraindicated. For more information on the clinical trial program, please visit http://www.clinicaltrials.gov.

“We are pleased to see our partner Daiichi Sankyo continue to advance CS-3150 through clinical development and into a well designed phase 3 pivotal trial in Japanese patients with essential hypertension,” said Michael M. Morrissey, Ph.D., president and chief executive officer of Exelixis. “While our strategic partners devote their time and resources to progressing out-licensed Exelixis-discovered compounds, our internal team is focused on continuing to build a global franchise for cabozantinib and participating meaningfully in the commercialization of cobimetinib in the United States.”

Daiichi Sankyo’s decision to take CS-3150 into phase 3 clinical development was guided by results from multiple phase 2 trials, including data from a randomized, placebo-controlled double-blind trial evaluating doses of CS-3150, and open-label eplerenone in 400 patients with hypertension. Daiichi Sankyo is currently reviewing those data in advance of potential submission for publication or presentation at a scientific forum later this year.

About Hypertension in Japan1

According to the 2012 Japan National Health and Nutrition Survey, there are an estimated 43 million patients with hypertension in the country, which accounts for 60% of men and 45% of women over the age of 30 in the general Japanese population.1 Just 30% of men and 40% of women with hypertension and treatment with antihypertensive medication typically achieve the goal of systolic and diastolic blood pressure lower than 140/90mm Hg.

Hypertension is one of the major risk factors for cardiovascular disease such as stroke and coronary heart disease, and the condition also raises the risk of chronic kidney disease and end-stage renal disease. Essential hypertension is the most common form of hypertension and has heterogeneous factors such as genetics and lifestyle habits, while secondary hypertension is associated with underlying disease factors. Essential hypertension is the most common form of hypertension, affecting 90% of hypertensive patients.

About CS-3150 (esaxerenone (r-INN))

CS-3150 (esaxerenone (r-INN)) is an oral, non-steroidal, selective antagonist of the mineralocorticoid receptor (MR), a nuclear hormone receptor implicated in a variety of cardiovascular and metabolic diseases. MR antagonists can be used to treat hypertension and congestive heart failure due to their vascular protective effects. Recent studies have also shown beneficial effects of adding MR antagonists to the treatment regimen for Type 2 diabetic patients with nephropathy. As a non-steroidal, selective MR antagonist, CS-3150 may have potential for the treatment of hypertension, diabetic nephropathy and congestive heart failure, and may provide protection from end organ damage due to vascular complications.

CS-3150 is one of the compounds identified during Exelixis’ research collaboration with Daiichi Sankyo, which the companies entered into in March 2006. Under the terms of the agreement, Exelixis granted Daiichi Sankyo an exclusive, worldwide license to certain intellectual property primarily relating to compounds that modulate MR. In exchange, Exelixis received a $20 million upfront payment, research funding for a joint research period, and the potential for substantial clinical development, regulatory and commercialization milestone payments, as well as double-digit royalties on sales. Since the conclusion of the joint research period in November 2007, Daiichi Sankyo has been responsible for all subsequent preclinical and clinical development, and will also oversee regulatory, manufacturing and commercialization activities for the compound.

About Exelixis

Exelixis, Inc. (NASDAQ:EXEL) is a biopharmaceutical company committed to the discovery, development and commercialization of new medicines with the potential to improve care and outcomes for people with cancer. Since its founding in 1994, three medicines discovered at

Exelixis have progressed through clinical development to receive regulatory approval. Currently, Exelixis is focused on advancing cabozantinib, an inhibitor of multiple tyrosine kinases including MET, AXL and VEGF receptors, which has shown clinical anti-tumor activity in more than 20 forms of cancer and is the subject of a broad clinical development program. Two separate formulations of cabozantinib have received regulatory approval to treat certain forms of kidney and thyroid cancer and are marketed for those purposes as CABOMETYX™ tablets (U.S. and EU) and COMETRIQ® capsules (U.S. and EU), respectively. Another Exelixis-discovered compound, COTELLIC® (cobimetinib), a selective inhibitor of MEK, has been approved in major territories including the United States and European Union, and is being evaluated for further potential indications by Roche and Genentech (a member of the Roche Group) under a collaboration with Exelixis. For more information on Exelixis, please visit www.exelixis.com or follow @ExelixisInc on Twitter.

Filing Data

Not available.

Contract

Not available.