



Dealdoc

Licensing and collaborative R&D agreement for novel peptide medicines

Boehringer Ingelheim
Zealand Pharma

Jul 28 2014

Licensing and collaborative R&D agreement for novel peptide medicines

Companies:	Boehringer Ingelheim Zealand Pharma
Announcement date:	Jul 28 2014
Amendment date:	Oct 09 2015
Deal value, US\$m:	402 : sum of upfront and milestone payments

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Details

Announcement date:	Jul 28 2014
Amendment date:	Oct 09 2015
Industry sectors:	Bigpharma Pharmaceutical
Exclusivity:	Exclusive
Asset type:	Compound
Therapy areas:	Cardiovascular Metabolic
Technology types:	Peptides
Deal components:	Collaborative R&D Licensing
Stages of development:	Preclinical
Geographic focus:	Worldwide

Financials

Deal value, US\$m:	402 : sum of upfront and milestone payments n/d : pre-defined development, regulatory and commercial milestones
Milestones, US\$m:	n/d : additional milestone payments if other products covered by the collaboration are advanced through development 402 : total project milestone payments
Royalty rates, %:	n/d : tiered royalties on global sales of products
Funding, US\$m:	n/d : Boehringer Ingelheim will fund the research, development and commercialisation of products under the agreement

Termsheet

October 2015

Zealand announced that Boehringer Ingelheim has selected a novel peptide therapeutic to be advanced into preclinical development under one of two ongoing collaboration agreements between the companies.

This collaboration, initiated in July 2014, covers a novel therapeutic peptide project from Zealand's preclinical portfolio with the aim of Zealand and Boehringer Ingelheim to join forces in the design and development of novel medicines for improved treatment of patients with cardio-metabolic diseases.

The biological target is not being disclosed.

Under the terms of the agreement, the companies have successfully advanced therapeutic peptides stemming from the collaboration towards preclinical development.

With the selection of a first preclinical candidate, Boehringer Ingelheim will now be responsible for the conduct and funding of the preclinical and potentially clinical development as well as commercialization.

The event has triggered a milestone payment from Boehringer Ingelheim to Zealand.

July 2014

Zealand Pharma and Boehringer Ingelheim announced a new global exclusive licence, research and development collaboration.

The collaboration covers a novel therapeutic peptide project from Zealand's portfolio of preclinical programs.

The aim is to develop novel medicines for improved treatment of patients with cardio-metabolic diseases.

The target is undisclosed.

The new collaboration reflects the confidence both parties have in each other and of their complimentary expertise in the research and development of new medicines.

Zealand and Boehringer Ingelheim will combine their research expertise for up to four and a half years focusing on the continued discovery, identification and characterization of novel peptide medicine candidates within the selected therapeutic target area of cardio-metabolic disease.

The companies will work together to advance the therapeutic peptides stemming from this research collaboration into preclinical development.

Boehringer Ingelheim will be responsible for the conduct of preclinical and clinical development as well as for the commercialization and solely fund the research, development and commercialization of products under the agreement.

Dependent upon the achievement of pre-defined development milestones, with the first at initiation of preclinical development, as well as regulatory and commercial milestones, Zealand is eligible to receive potential payments of up to a total of EUR 295 million for the first compound, developed and marketed under the collaboration.

Zealand will be eligible to receive additional milestones for other compounds advanced.

Further, Zealand is entitled to research funding plus tiered royalties on global sales of products stemming from the collaboration.

Zealand retains co-commercialization rights in Scandinavia.

Press Release

October 2015

Zealand Pharma Meets Development Milestone In Collaboration With Boehringer Ingelheim

COPENHAGEN, Denmark, Oct. 9, 2015 (GLOBE NEWSWIRE) -- Zealand announces that Boehringer Ingelheim has selected a novel peptide therapeutic to be advanced into preclinical development under one of two ongoing collaboration agreements between the companies. This collaboration, initiated in July 2014, covers a novel therapeutic peptide project from Zealand's preclinical portfolio with the aim of Zealand and Boehringer Ingelheim to join forces in the design and development of novel medicines for improved treatment of patients with cardio-metabolic diseases. The biological target is not being disclosed.

Under the terms of the agreement, the companies have successfully advanced therapeutic peptides stemming from the collaboration towards preclinical development. With the selection of a first preclinical candidate, Boehringer Ingelheim will now be responsible for the conduct and funding of the preclinical and potentially clinical development as well as commercialization. The event has triggered a milestone payment from Boehringer Ingelheim to Zealand.

Commenting on the milestone achievement, Keld Fosgerau, acting Senior Vice President, Head of Research at Zealand said: "The selection for preclinical development of a lead peptide therapeutic arising from our second fruitful research collaboration with Boehringer Ingelheim is an important milestone. It demonstrates the impact of Zealand's approach to peptide science in the cardio-metabolic space and further substantiates our portfolio of outlicensed products, which is developing alongside our growing proprietary pipeline."

Zealand and Boehringer signed a first collaboration agreement in June 2011, which is ongoing. This covers the development and commercialization of novel glucagon/GLP-1 dual-acting peptide therapeutics to treat patients with Type 2 diabetes and/or obesity. Under this collaboration, Boehringer Ingelheim has a lead development candidate in preclinical development.

Financial outlook for 2015 and terms of the collaborations with Boehringer Ingelheim

The announced milestone is associated with a payment of EUR 3 million to Zealand. The payment does not change Zealand's financial outlook for 2015, which includes expected total milestone payments of EUR 21 million.

Dependent upon the achievement of pre-defined development, regulatory and commercial milestones, Zealand is eligible to receive potential payments of up to a total of EUR 295 million for the first compound, developed and marketed under this collaboration. Under the first collaboration agreement, Zealand is eligible to receive potential remaining development, regulatory and commercial milestones of up to a total of EUR 365 million. Under both agreements, Zealand is also entitled to royalties on global sales of products stemming from the collaborations, while retaining co-commercialization rights in Scandinavia.

For further information, please contact:

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About Zealand Pharma

Zealand Pharma A/S (Nasdaq Copenhagen: ZEAL) ("Zealand") is a medicinal biotech company with leading expertise in the identification, design and development of novel peptide medicines. Zealand has a proprietary pipeline of novel drug candidates and a portfolio of products and projects under license collaborations with Sanofi, Helsinn Healthcare and Boehringer Ingelheim - primarily in the fields of cardio-metabolic diseases and acute care indications.

The proprietary pipeline includes; danegaptide for ischemic reperfusion injuries in Phase II development, ZP1848 for Short Bowel Syndrome in Phase II development and the stable glucagon analogue, ZP4207 as a single-dose rescue pen for severe hypoglycemia in preparation for Phase II, and ZP4207 as multiple-dose use for the correction of mild to moderate hypoglycemia in evaluation for the next clinical development step after Phase I, as well as several preclinical peptide therapeutics.

Zealand has invented lixisenatide, a once-daily prandial GLP-1 agonist, which is marketed globally (ex-US) by Sanofi for the treatment of Type 2 diabetes and since end September 2015 has been under review by the FDA in the US. The license agreement with Sanofi also covers a single-product combination of lixisenatide and insulin glargine (Lantus(r)) which is on track for regulatory submission in the US in Q4 2015 and in Europe in Q1 2016.

The company is based in Copenhagen (Glostrup), Denmark. For further information about Zealand's business and activities, please visit: www.zealandpharma.com or follow us on Twitter @ZealandPharma

July 2014

Zealand Pharma (ZEAL.CO), Boehringer Ingelheim Corporation Strike \$402 Million Peptide Pact

Zealand And Boehringer Ingelheim Sign Second Collaboration Agreement To Advance Novel Peptide Medicines Company Announcement

No. 11/2014

Zealand eligible to receive up to EUR 295 million in potential milestone payments for the first commercialized product plus research funding and royalties. In 2014, payments of EUR 5.6 million to Zealand Research and development agreement for a novel peptide project against an un-disclosed cardio-metabolic target from Zealand's preclinical portfolio Boehringer Ingelheim obtains global exclusive development and commercial rights to products under the agreement, with Zealand retaining co-commercialization rights in Scandinavia COPENHAGEN, Denmark and INGELHEIM, Germany, July 28, 2014 (GLOBE NEWSWIRE) -- Zealand Pharma ("Zealand") (NASDAQ OMX Copenhagen: ZEAL), a company specialized in the discovery, design and development of peptide medicines, and Boehringer Ingelheim, one of the world's leading pharmaceutical companies, today jointly announced a new global exclusive licence, research and development collaboration. The collaboration covers a novel therapeutic peptide project from Zealand's portfolio of preclinical programs. The aim is to develop novel medicines for improved treatment of patients with cardio-metabolic diseases. The target is undisclosed.

This marks the second collaboration between Zealand and Boehringer Ingelheim following the first agreement, which was signed in June 2011. The first collaboration is ongoing for the development and commercialization of novel glucagon/GLP-1 dual-acting peptide therapeutics to treat patients with Type 2 diabetes and/or obesity. The new collaboration reflects the confidence both parties have in each other and of their complimentary expertise in the research and development of new medicines.

Commenting on the announcement, David H. Solomon, President and CEO of Zealand, said: "This second agreement secures additional funding and attractive value potential to Zealand. It demonstrates our strong partner relations with Boehringer Ingelheim, leveraging Zealand's expertise in the design and development of therapeutic peptides to now cover an additional target in the cardio-metabolic disease area. We look forward to working with Boehringer Ingelheim towards selection of the first preclinical peptide therapeutic to be advanced in development under this new agreement."

Dr Michel Pairet, Boehringer Ingelheim's Senior Vice President Corporate Division Research and Development non-clinical, commented: "Partnering is key to our business strategy and the relationship with Zealand is a long-term and important one. We are, therefore, extremely pleased to enter into this new agreement with Zealand, a company recognised as experts in their field, which will further complement and strengthen our own discovery and development efforts in the area of cardio-metabolic diseases."

Under the new agreement, Zealand and Boehringer Ingelheim will combine their research expertise for up to four and a half years focusing on the continued discovery, identification and characterization of novel peptide medicine candidates within the selected therapeutic target area of cardio-metabolic disease. The companies will work together to advance the therapeutic peptides stemming from this research collaboration into preclinical development. Boehringer Ingelheim will be responsible for the conduct of preclinical and clinical development as well as for the commercialization and solely fund the research, development and commercialization of products under the agreement.

Dependent upon the achievement of pre-defined development milestones, with the first at initiation of preclinical development, as well as regulatory and commercial milestones, Zealand is eligible to receive potential payments of up to a total of EUR 295 million for the first compound, developed and marketed under the collaboration. Zealand will be eligible to receive additional milestones for other compounds advanced. Further, Zealand is entitled to research funding plus tiered royalties on global sales of products stemming from the collaboration. Zealand retains co-commercialization rights in Scandinavia.

Zealand's financial outlook for 2014

The new agreement with Boehringer Ingelheim is expected to positively affect Zealand's revenue and other operating income by a total of DKK 42 (EUR 5.6) million in 2014.

The company therefore raises its full year revenue guidance to DKK 133 (EUR 18) million (from DKK 96 (EUR 13) million) and lowers its expectations on net operating expenses in 2014 to DKK 195-205 (EUR 25-28) million (from DKK 200-210 (EUR 26-29)).

Filing Data

Not available.

Contract

Not available.