Current Agreements

Dealdoc

Collaboration agreement for NASH clinical diagnostic tool

Galmed Pharmaceuticals
Zora Biosciences

Dec 19 2013

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Companies:	Galmed Pharmaceuticals Zora Biosciences
Announcement date:	Dec 19 2013
Deal value, US$m:	n/d

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Details

Announcement date:	Dec 19 2013
Start date:	Dec 19 2013
Industry sectors:	Diagnostic Pharmaceutical Research tools
Asset type:	Technology
Therapy areas:	Metabolic » Fatty liver Metabolic » Liver disease » Nonalcoholic steatohepatitis (NASH)
Technology types:	Biomarkers Diagnostics » Companion Diagnostics » Molecular diagnostics
Deal components:	Collaborative R&D Licensing

Financials

Deal value, US$m:	n/d
More details:	Obligated to pay to-be-agreed upon fees to Zora in respect of its lipidomic analysis activities, and if such activities generate patentable intellectual property for Zora, then we will receive a reimbursement of 40% of such fees.

Termsheet

Memorandum of understanding with Zora Biosciences to explore opportunities to collaborate in order to develop a NASH clinical diagnostic tool, as well as a clinical diagnostic tool for patients receiving aramchol treatment.

Zora performs lipidomic profiling analyses in order to generate molecular lipid quantification data.

According to the Zora MOU, in connection with our planned Phase IIb clinical trial of aramchol, we will collect and provide to Zora liver tissue samples from biopsies and serum samples from the patients screened and enrolled in the Israeli-based centers in the trial and Zora will perform lipidomic profiling analysis based on such samples.

Once Zora has performed its analysis, Zora is permitted to verify its results by comparing them to the results of the liver biopsies that will be taken from the trial participants and from their MRIs.

We expect this to enable Zora to evaluate the performance of its lipidomic profiles and develop a NASH disease clinical diagnostic tool and generate lipidomic profiles correlated with disease progression of patients.

We also expect that this will enable Zora to develop a clinical diagnostic tool for patients receiving aramchol treatment, which would be intellectual property owned by us.

We will not receive any financial payment from Zora.

However, we will be obligated to pay to-be-agreed upon fees to Zora in respect of its lipidomic analysis activities, and if such activities generate patentable intellectual property for Zora, then we will receive a reimbursement of 40% of such fees.

According to the Zora MOU, we will own all clinical data and Zora will own all lipidomic data, each as generated by our collaboration.

We also agreed to grant Zora a free license to use such clinical data only to develop biomarkers and related diagnostics in the field of NASH.

Zora will grant to us a free license to use their lipidomic data generated by the clinical trial for developing a clinical diagnostic tool for patients receiving treatment with aramchol.

Zora will also grant us a right of first discussion, exercisable upon completion of the Phase IIb clinical trial, to enter into a business transaction with Zora, separate from the transaction and relationship contemplated in the Zora MOU, regarding the commercial exploitation of its NASH disease clinical diagnostic tool based upon the data generated during the collaboration.

We agreed to enter into a definitive agreement with Zora on the basis of the principles detailed in the Zora MOU, but no such definitive agreement has been executed as of yet.

The Zora MOU is silent as to term, termination and whether or not it is binding.

Press Release

Not available.

Filing Data

S1 abstract - 2014

On December 19, 2013, we entered into a memorandum of understanding with Zora Biosciences, or the Zora MOU, to explore opportunities to collaborate in order to develop a NASH clinical diagnostic tool, as well as a clinical diagnostic tool for patients receiving aramchol treatment. Zora performs lipidomic profiling analyses in order to generate molecular lipid quantification data.

According to the Zora MOU, in connection with our planned Phase IIb clinical trial of aramchol, we will collect and provide to Zora liver tissue samples from biopsies and serum samples from the patients screened and enrolled in the Israeli-based centers in the trial and Zora will perform lipidomic profiling analysis based on such samples. Once Zora has performed its analysis, Zora is permitted to verify its results by comparing them to the results of the liver biopsies that will be taken from the trial participants and from their MRIs. We expect this to enable Zora to evaluate the performance of its lipidomic profiles and develop a NASH disease clinical diagnostic tool and generate lipidomic profiles correlated with disease progression of patients. We also expect that this will enable Zora to develop a clinical diagnostic tool for patients receiving aramchol treatment, which would be intellectual property owned by us.

We will not receive any financial payment from Zora. However, we will be obligated to pay to-be-agreed upon fees to Zora in respect of its lipidomic analysis activities, and if such activities generate patentable intellectual property for Zora, then we will receive a reimbursement of 40% of such fees.

According to the Zora MOU, we will own all clinical data and Zora will own all lipidomic data, each as generated by our collaboration. We also agreed to grant Zora a free license to use such clinical data only to develop biomarkers and related diagnostics in the field of NASH. Zora will grant to us a free license to use their lipidomic data generated by the clinical trial for developing a clinical diagnostic tool for patients receiving treatment with aramchol. Zora will also grant us a right of first discussion, exercisable upon completion of the Phase IIb clinical trial, to enter into a business transaction with Zora, separate from the transaction and relationship contemplated in the Zora MOU, regarding the commercial exploitation of its NASH disease clinical diagnostic tool based upon the data generated during the collaboration. We agreed to enter into a definitive agreement with Zora on the basis of the principles detailed in the Zora MOU, but no such definitive agreement has been executed as of yet. The Zora MOU is silent as to term, termination and whether or not it is binding.

Contract

Memorandum of Understanding

Between

Galmed Pharmaceuticals and Zora Biosciences

Pursuant to discussions held between our companies. Galmed Pharmaceuticals (hereinafter “Galmed”) and Zora Biosciences (hereinafter “Zora”) agree to explore opportunities to collaborate in the field of lipidomic profiling.

Galmed develops innovative, proprietary drugs (fatty acid bile-acid conjugates) for the treatment of cholesterol and liver diseases. The most advanced compound in the series is Aramchol (arachidyl amido cholanoic acid), which is currently in clinical studies.

Zora develops lipid-based biomarkers for diagnostic industry and provides lipidomic services for pharmaceutical research.

Therefore, this Memorandum of Understanding aims at setting forth the general terms and conditions upon which Galmed and Zora are prepared to enter in further collaboration agreement.

- Scope of the study:

o Develop a NASH disease clinical diagnostic tool which IP will be owned by Zora

o Develop a clinical diagnostic tool for patients on Aramchol treatment (companion diagnostic) which IP will be owned by Galmed .

- Overview:

o Galmed intends to initiate a multi centre multi nation phase IIb study aiming to evaluate the Efficacy and Safety of Aramchol Versus Placebo in Patients With Non-Alcoholic Steatohepatitis (“NASH”).

o Galmed will collect liver tissue samples from biopsies and serum samples from patients enrolled in the Israeli based centers in the study, according to specifications which will be provided by Zora, at baseline and at the end of the phase IIb study. Zora will perform lipidomic profiling analysis based on the tissue and serum samples taken from the patients.

- Contribution of parties:

o Galmed will perform and provide access to biopsy and serum samples from the phase IIb patients (patients screened and enrolled in Israel to the study) and will provide patients clinical data (including liver biopsy results and MRI results).

o Zora will provide sampling methods and will perform lipidomic profiling to generate molecular lipid quantification data (“lipidomic data”).

o The lipidomic analyses will be executed with a Fee-for-service principle. In case patentable IP is generated for Zora, 40 % of the fees shall be compensated to Galmed.

- Expected results/outcomes:

o From Lipidomic data generated throughout the collaboration, the parties expect a) to develop a NASH disease clinical diagnostic tool and generate Lipidomic profiles correlated with disease progression of patients which IP will be owned by Zora. b) Develop a clinical diagnostic tool for patients on Aramchol treatment (companion diagnostic) which IP will be owned by Galmed.

- Exploitation of data and results

o Each parties remains sole owner of their background IP.

o Galmed will be sole owner of clinical data generated throughout the collaboration. Galmed will grant Zora a free license for using clinical data associated to patients in the frame only for developing biomarkers and related diagnostic in the field of NASH.

o Zora will grant Galmed for a free license to use Lipidomic data generated throughout the study only for developing a clinical diagnostic tool for patients on Aramchol treatment.

o Upon successful completion of the phase IIB study, Zora will grant Galmed for a right of first discussion to enter business transaction regarding commercial exploitation of Zora’s proprietary NASH disease clinical diagnostic tool based upon the data generated during the collaboration.

o Rights for mutual publications.

The principles of the project and detailed arrangements will be set forth in a definitive agreement between the parties.