Current Agreements

Dealdoc

Development agreement for AtuRNAi for open-angle glaucoma

Quark Pharmaceuticals
Pfizer

May 03 2012

Development agreement for AtuRNAi for open-angle glaucoma

Companies:	Quark Pharmaceuticals Pfizer
Announcement date:	May 03 2012
Deal value, US$m:	165 : sum of transaction for amended agreement

Details

Announcement date:	May 03 2012
Industry sectors:	Bigpharma Biotech Pharmaceutical
Therapy areas:	Ophthalmics Regenerative medicine » Tissue regeneration
Technology types:	RNA therapeutics Small molecules
Deal components:	Development Licensing
Stages of development:	Preclinical

Financials

Deal value, US$m:	165 : sum of transaction for amended agreement

Termsheet

Quark Pharmaceuticals has announced it has amended its existing exclusive Licensing Agreement with Pfizer.

This amendment will enable Quark to perform a Phase 2a clinical study to assess the effect of PF-655 in a new indication, looking at visual function in patients with moderate and advanced Open-Angle Glaucoma (OAG).

PF-655 incorporates Silence's AtuRNAi technology and was sub-licensed to Pfizer by Quark in 2006, and on which Silence is entitled to receive a share of milestones and royalties that may be earned by Quark in the future on this compound.

The OAG study will be conducted in parallel with a Phase 2b study of PF-655 in diabetic macular oedema.

Silence has previously announced that it stood to receive up to $95m from Quark in relation to its licensing agreement with Pfizer.

As a result of this amendment to the Quark/Pfizer license, Silence anticipates its share of these payments could now reach $120m.

Silence has previously announced the receipt of $6m from Quark in relation to this licence.

The announcement issued by Quark Pharmaceuticals is shown below:

Quark Pharmaceuticals announced that Quark and Pfizer have amended their existing exclusive Licensing Agreement in order to enable Quark to perform a Phase 2a clinical study to assess the effect of PF-655 on visual function in patients with moderate and advanced Open-Angle Glaucoma (OAG).

This study will be conducted in parallel with an ongoing Phase 2b study (QRK202) in diabetic macular edema (DME).

The OAG study will evaluate the potential of PF-655 to enhance visual function in glaucoma.

Under the amended agreement, should Pfizer assume development and potential commercialization of PF-655 in either or both indications following review of the Phase 2a PF-655 data, Quark will receive option exercise payments and be will eligible to receive development and regulatory milestones specific to each indication, as well as sales milestones and royalties.

Quark may be eligible to receive additional total payments of up to approximately $165 million associated with development and approval of PF-655 for OAG.

Preclinical studies of PF-655 conducted by Quark suggest the potential of the compound as a neuroprotective and potentially neuroenhancing agent in diseases such as OAG, by preventing optic neural cell apoptosis and stimulating optic neural cell regeneration.

In addition, in a Phase 2a study in patients with DME (Pfizer DEGAS study #B0451004), repeated injections of PF-655 showed a dose-dependent increase in visual acuity independent of changes in retinal thickness.

The beneficial effects of PF-655 on visual function may potentially be due to effects on retinal cells themselves, rather than on vascular permeability.

Press Release

Silence Therapeutics plc' Partner, Quark Pharmaceuticals Inc., Extends its Agreement With Pfizer Inc. (PFE) to Develop one of Its Compounds Containing Silence's AtuRNAi in a New Indication

Silence Therapeutics Plc (AIM: SLN), a leading international RNAi therapeutics company, notes that its partner, Quark Pharmaceuticals, has announced it has amended its existing exclusive Licensing Agreement with Pfizer. This amendment will enable Quark to perform a Phase 2a clinical study to assess the effect of PF-655 in a new indication, looking at visual function in patients with moderate and advanced Open-Angle Glaucoma (OAG). PF-655 incorporates Silence's AtuRNAi technology and was sub-licensed to Pfizer by Quark in 2006, and on which Silence is entitled to receive a share of milestones and royalties that may be earned by Quark in the future on this compound.

The OAG study will be conducted in parallel with a Phase 2b study of PF-655 in diabetic macular oedema.

Silence has previously announced that it stood to receive up to $95m from Quark in relation to its licensing agreement with Pfizer. As a result of this amendment to the Quark/Pfizer license, Silence anticipates its share of these payments could now reach $120m. Silence has previously announced the receipt of $6m from Quark in relation to this licence.

Commenting on the announcement, Tony Sedgwick, Chief Executive Officer of Silence, said: "This is an exciting development for Silence. This will create a fifth external clinical program using Silence's IP and AtuRNAi, which is funded and managed by one of our partners. This will increase the potential share of milestones and royalties that Silence can earn under its agreement with Quark and is a further validation of the Silence technology."

The announcement issued by Quark Pharmaceuticals is shown below:

Quark Pharmaceuticals Announces Phase 2a Study of PF--04523655 (PF-655) in Patients With Moderate and Advanced Open-Angle Glaucoma (OAG)

FREMONT, Calif., May 1, 2012 - Quark Pharmaceuticals, Inc., today announced that Quark and Pfizer have amended their existing exclusive Licensing Agreement in order to enable Quark to perform a Phase 2a clinical study to assess the effect of PF-655 on visual function in patients with moderate and advanced Open-Angle Glaucoma (OAG). This study will be conducted in parallel with an ongoing Phase 2b study (QRK202) in diabetic macular edema (DME). The OAG study will evaluate the potential of PF-655 to enhance visual function in glaucoma. Under the amended agreement, should Pfizer assume development and potential commercialization of PF-655 in either or both indications following review of the Phase 2a PF-655 data, Quark will receive option exercise payments and be will eligible to receive development and regulatory milestones specific to each indication, as well as sales milestones and royalties. Quark may be eligible to receive additional total payments of up to approximately $165 million associated with development and approval of PF-655 for OAG.

Preclinical studies of PF-655 conducted by Quark suggest the potential of the compound as a neuroprotective and potentially neuroenhancing agent in diseases such as OAG, by preventing optic neural cell apoptosis and stimulating optic neural cell regeneration. In addition, in a Phase 2a study in patients with DME (Pfizer DEGAS study #B0451004), repeated injections of PF-655 showed a dose-dependent increase in visual acuity independent of changes in retinal thickness. The beneficial effects of PF-655 on visual function may potentially be due to effects on retinal cells themselves, rather than on vascular permeability.

The OAG study will be a Phase 2a, multi-center, double-masked, randomized, repeat dose, safety, tolerability and efficacy study in up to 108 patients with moderate and advanced OAG. In addition, Quark is currently conducting a Phase 2b study (QRK202) in DME patients testing higher doses of PF-655 alone and in combination with Lucentis(R) to further evaluate the safety and efficacy of PF-655 in DME and to determine

the optimal dose for pivotal Phase 3 studies.

Daniel Zurr, Ph.D. President and Chief Executive Officer of Quark stated: "We are very excited to evaluate the effect of PF-655 on visual loss in glaucoma in future clinical studies. The mechanism of action and biological activity of PF-655 are novel and its axon regenerating effects may provide a long awaited breakthrough in the treatment of glaucoma. We are pleased and grateful to our partner, Pfizer, for their support in pursuing this new indication."

About Quark Pharmaceuticals, Inc.

Quark Pharmaceuticals, Inc. is a clinical-stage pharmaceutical company engaged in discovering and developing novel RNA interference (RNAi)-based therapeutics. The Company has a fully integrated drug development platform that spans therapeutic target identification based on its proprietary gene discovery science and technology, to clinical drug development. The Company has been focusing on RNAi-based therapeutics for the treatment of diseases associated with oxidative stress and ischemic injury. Quark has three product candidates in clinical development in six different indications of which five are in Phase 2.

Quark is committed to leveraging a broad research pipeline of short interfering RNA (siRNA) drug candidates and novel siRNA structures to develop additional RNAi drug candidates.

Quark is headquartered in Fremont, California and operates research and development facilities in Boulder, Colorado and Ness-Ziona, Israel. Additional information is available at http://www.quarkpharma.com.

Notes for editors

About Silence Therapeutics plc (http://www.silence-therapeutics.com)

Silence Therapeutics plc (AIM: SLN) is a leading biotechnology company dedicated to the discovery, development and delivery of targeted, systemic RNA interference (RNAi) therapeutics for the treatment of serious diseases. Silence offers one of the most comprehensive short interfering RNA (siRNA) therapeutic platforms available today based on a strong intellectual property portfolio and large clinical safety database. Silence's clinical siRNA product pipeline is one of the broadest in the industry. The Company possesses multiple proprietary siRNA delivery technology platforms including AtuPLEX, DACC and DBTC. AtuPLEX enables the broad functional delivery of siRNA molecules to targeted diseased tissues and cells, while increasing their bioavailability and intracellular uptake. The DACC delivery system allows functional delivery of siRNA molecules selectively to the lung endothelium with a long duration of target mRNA and protein knock-down. The DBTC delivery system enables functional delivery of siRNA molecules selectively to liver cells including hepatocytes. Additionally, the Company has a platform of novel siRNA molecules based around its AtuRNAi chemical modification technology, which provides a number of advantages over conventional siRNA molecules. Silence's unique RNAi assets also include structural features for RNAi molecules and specific design rules for increased potency and reduced off-target effects of siRNA sequences.

The Company's lead internal drug candidate is Atu027, a liposomal formulation in clinical development for systemic cancer indications and one of the most clinically advanced RNAi therapeutic candidates in the area of oncology. Atu027 incorporates two of the Company's technologies, AtuRNAi and AtuPLEX. Silence is currently conducting an open-label, single-centre, dose-escalation Phase I study with Atu027 in patients with advanced solid tumors involving single, as well as repeated, intravenous administration. Encouraging interim safety and pharmacokinetic data were presented at the American Society of Clinical Oncology Annual Meeting in June 2011. The study is expected to be completed in the first half of 2012.

The Company's RNAi therapeutic platform has received key validation through multiple partnerships with pharmaceutical companies including AstraZeneca, Dainippon Sumitomo, Pfizer/Quark, and Novartis/Quark. Silence is actively pursuing the establishment of additional partnerships. Silence Therapeutics has operations in both Berlin and London.

Filing Data

Not available.

Contract

Not available.