



Inotek Pharmaceuticals Announces Positive End-of-Phase 2 Meeting with FDA and Phase 3 Development Strategy for Trabodenoson, a Novel Treatment for Glaucoma

July 23, 2015

--Pivotal Studies Designed to Show Superiority to Placebo--

--1st Phase 3 Study to Commence in 4Q15 with Top-line Data In 2016--

--Conference Call Scheduled for 8:30AM ET--

LEXINGTON, Mass.--(BUSINESS WIRE)--Jul. 23, 2015-- Inotek Pharmaceuticals Corporation (NASDAQ: ITEK), a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of therapies for ocular diseases, today announced the Phase 3 development strategy of its lead glaucoma drug, trabodenoson, a first-in-class selective adenosine mimetic designed to restore the eye's natural pressure control mechanism. Based on feedback from a recent End of Phase 2 meeting with the US Food and Drug Administration (FDA), Inotek is in final preparation stages to commence its first Phase 3 trial to support a New Drug Application (NDA) for trabodenoson.

"Our End-of-Phase 2 meeting was a critical milestone for advancing the development of trabodenoson. We are pleased with the agency's guidance on the pivotal trial design which will enable a more efficient registration path to potentially bring this novel glaucoma therapy to market for the benefit of patients," said David P. Southwell, President and Chief Executive Officer. "We expect to commence our first Phase 3 trial in 4Q and look forward to data in 2016."

The trial design for the first pivotal study is a five-arm superiority trial that will include three doses of trabodenoson. These doses were selected to optimize lowering of intraocular pressure while maintaining the good tolerability observed in Phase 2 trials. The primary efficacy endpoint of the study is the reduction of intraocular pressure (IOP), statistically superior as compared to placebo. A comparator arm of timolol will also be included for study validation, but not for statistical comparison.

"There is a major unmet medical need for a well-tolerated and effective therapy with a new mechanism of action for glaucoma," said Rudolf Baumgartner, M.D, Chief Medical Officer of Inotek. "Our overall program will consist of three clinical trials encompassing a total subject exposure of 1300 patients. Our previous Phase 2 studies have demonstrated that trabodenoson's efficacy improves over time, and with increases in dose. A benefit of the Phase 3 superiority design is that we can investigate more than one dose of trabodenoson, allowing us to further optimize the drug's clinical and safety profile."

In Phase 2 trials, trabodenoson demonstrated a dose-response for intraocular pressure lowering in ocular hypertension and primary open angle glaucoma patients. After 14 days of treatment, both the 200mg and 500mg doses of trabodenoson demonstrated a statistically significant reduction ($P < 0.05$) in IOP relative to the matched placebo group. After 28 days of treatment, the 500mg dose continued to demonstrate a statistically significant reduction in IOP relative to placebo, in the range of other glaucoma therapies. Across all trials, the efficacy of trabodenoson has remained consistent, with no waning effect observed, and the IOP reduction was consistent across different patient sub-populations. Trabodenoson has also been well tolerated with no serious adverse events. In patients with glaucoma or ocular hypertension, the rate of conjunctival hyperemia (redness in the eye), a side-effect commonly associated with other mechanisms used to treat glaucoma, was not affected by trabodenoson treatment.

William McVicar, Ph.D., Chief Scientific Officer, commented, "Glaucoma is an optic nerve neuropathy, where vision is lost due to the death of the retinal ganglion cells which carry the visual signal from the retina to the brain. While trabodenoson data indicated IOP reductions in the range of current therapies, we have also demonstrated in animals that trabodenoson can protect these neural cells from high ocular pressure injury. This data supports that A1 agonism not only reduces IOP but may also have a neuroprotective role in the retina. If we are able to demonstrate the same neuroprotective effects of trabodenoson in humans, we believe trabodenoson has the potential to significantly change how glaucoma is managed, potentially supporting earlier intervention in a substantially larger population of patients."

Conference Call Information

Inotek will host a conference call and webcast today, July 23, 2015, at 8:30 am (EDT) to discuss the trabodenoson development strategy. To participate in the conference call, please dial (866) 430-2017 (U.S.) or (704) 908-0413 (international) five minutes prior to the start of the call and provide the Conference ID: 93395336, or access the listen-only webcast by visiting the Company's website www.inotekpharma.com.

An archive of today's conference call will be available shortly after the conclusion of the call and accessed by dialing (855) 859-2056 (U.S.) or (404)

537-3406 and referencing the Conference ID: 93395336, or by visiting Inotek's website. The audio replay will be available for two weeks following the call and the webcast for thirty days.

About Inotek Pharmaceuticals Corporation

Inotek Pharmaceuticals is a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of therapies for glaucoma and other eye diseases. Our lead product candidate, trabodenoson, is a first-in-class selective adenosine mimetic developed in Inotek's laboratories designed to restore the eye's natural pressure control mechanism. The development of trabodenoson monotherapy delivered in a once-daily eye drop formulation will be followed by a fixed-dose combination of trabodenoson with latanoprost. Additionally, the Company is evaluating the potential for selective adenosine mimetics to address optic neuropathies and other degenerative retinal diseases.

Forward-Looking Statements

This press release contains forward-looking statements, which are subject to substantial risks, uncertainties and assumptions. You should not place reliance on these statements. Forward-looking statements include information concerning the proposed offerings. These statements often include words such as "believe," "expect," "anticipate," "intend," "plan," "estimate," "seek," "will," "may" or similar expressions. Although the Company believes that the expectations reflected in the forward-looking statements are reasonable, the Company cannot guarantee such outcomes. Accordingly, you should not place undue reliance on these forward-looking statements. All such statements speak only as of the date made, and the Company undertakes no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise.



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Source: Inotek Pharmaceuticals Corporation

Inotek Contact:

Claudine Prowse, Ph.D., 781-552-4305
Vice President, Strategy and Investor Relations Officer
cprowse@inotekpharma.com

or

Media Contact:

MacDougall Biomedical
Karen Sharma, 781-235-3060
ksharma@macbiocom.com