ArQule lung cancer treatment one step closer to market

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Woburn-based biotech ArQule Inc. and New Jersey pharmaceutical firm Daiichi Sankyo Co. Ltd. are heading toward a Phase 3 clinical trial of their treatment for non-small cell lung cancer, and Daiichi Sankyo is filing a Special Protocol Assessment (SPA) with the U.S. Food and Drug Administration to guide the design of the trial.

The trial will ultimately evaluate the efficacy of the two companies' co-developed small molecule inhibitor ARQ 197 as a non-small cell lung cancer therapeutic. The SPA, which will direct the trial's design and analysis to support a New Drug Application, will address ARQ 197, used in conjunction with another drug, erlotinib, as compared to erlotinib plus placebo.

ARQ 197 is an orally available, small molecule inhibitor of the c-Met receptor tyrosine kinase. Erlotinib, marketed as Tarceva by Genentech USA Inc., is an inhibitor of the EGFR tyrosine kinase.

A Phase 2 trial conducted earlier this year returned positive results for ARQ 197 [1], used in conjunction with erlotinib – a median of 16.1 weeks of progression-free survival, compared with 9.7 weeks for the patients that received erlotinib with a placebo.

ArQule (Nasdaq: ARQL) signed a license, co-development and co-commercialization deal with Daiichi Sankyo [2] in 2008, outlining their ARQ 19

7 co-development efforts worldwide, excluding the countries – Japan, China, South Korea and Taiwain – holding exclusive development and commercialization rights.

SOURCE [3]

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http://www.mdtmag.com/news/2010/08/arqule-lung-cancer-treatment-one-step-closer-market

Links:
[1] http://www.masshightech.com/stories/2010/03/29/daily31-ArQule-drug-candidate-shows-promise-in-lung-cancer-therapy.html

[2] http://www.masshightech.com/stories/2008/11/10/daily5-ArQule-development-deal-with-Daiichi-Sankyo-delivers-75M.html
[3] http://www.masshightech.com/stories/2010/08/02/daily20-ArQule-lung-cancer-treatment-one-step-closer-to-market.html