Updated Results of Phase 1b Study of KSI-301, an Anti-VEGF Antibody Biopolymer Conjugate with Extended Durability, in wAMD, DME, and RVO

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Purpose:
An ongoing Phase 1b clinical trial (NCT03790852), has demonstrated promising initial safety, efficacy and durability of intravitreal KSI-301, a novel anti-VEGF antibody biopolymer conjugate designed for improved intraocular durability, in patients with wAMD, DME and RVO. Data with extended patient follow-up of 32 weeks and beyond, as well as follow-up after multiple re-treatments over time will be reported at the meeting.

Methods:
This is a multicenter, randomized, open-label, Phase 1b study in treatment-naive subjects with wAMD, DME or RVO followed over 72 weeks. Patients receive 3 initial monthly doses of either 2.5 mg or 5 mg of KSI-301 with additional treatment given according to disease-specific, protocol-specified retreatment criteria. Preliminary results for patients that have reached Week 24 (n=80) as of January 21, 2020 are presented in this abstract. Updated results will be provided at the meeting.

Results:
The phase 1b study is ongoing, with 121 patients recruited across all three cohorts. Ocular safety of KSI-301 is encouraging with no reports of intraocular inflammation and no drug-related adverse events after 420 doses. Mean change in BCVA at Week 24 was +5.9 letters in wAMD (n=31, baseline 64.2), +6.8 letters in DME (n=19, baseline 70.4) and +22.2 letters in RVO (n=30, baseline 52.1). Mean change in CST was -58 microns (µm) in wAMD (baseline 415), -133 µm in DME (baseline 434) and -350 µm in RVO (baseline 712). 84%, 76% and 53% of wAMD, DME and RVO patients, respectively, have been extended to 4 months or longer after the last loading dose without receiving retreatment. Additionally, 55% of wAMD patients have achieved a 6-month interval before a mandated first treatment, and 64% of DME patients have reached 6 months or longer without retreatment.

New data with longer follow-up will be presented for the first time at the meeting.

Conclusions:
Ongoing results of the Phase 1b study demonstrate that treatment with KSI-301 results in excellent treatment outcomes in patients with wAMD, DME and RVO. KSI-301 has an excellent safety profile and biological durability. Recruitment of a pivotal study (DAZZLE) in wAMD comparing KSI-301 every 3-5 months vs aflibercept is underway.