Preliminary Results from the First in Human Study of Activin A Inhibitor, STM 434, in Patients with Granulosa Cell Ovarian Cancer and Other Advanced Solid Tumors

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CONCLUSIONS

- Single agent STM 434 showed an acceptable safety profile in patients with advanced solid tumors and early evidence of clinical activity in granulosa ovarian cancer.
- STM 434/434 add-in linear (PK) that support an every other week dosing schedule.
- Increasing doses of STM 434 were associated with decreased FSH suggestive of PO target engagement.
- Increasing doses of STM 434 resulted in modulation of cancer cachexia as assessed by increased LBM and 6-MWD.
- The maximum tolerated dose has not been determined and dose escalation is ongoing to determine the recommended phase 2 dose in granulosa ovarian cancer and other solid tumors.

RESULTS

- Using a 3+3 dose escalation design, the safety and pharmacokinetics (PK) of STM 434 were evaluated in 35 patients (pts) continued until disease progression or unacceptable toxicity. CT scans were performed every 8-12 weeks.
- Objective: To evaluate the safety, PK, pharmacodynamics (PD), and efficacy of STM 434 in patients with advanced solid tumors.
- To evaluate the effects of STM 434 on lean body mass by DEXA scan and muscle function by 6 minute walk distance.

METHODS

- STM 434 Monotherapy, n=25
- STM 434 + DOX, n=10

Table 5. Adverse Events of Interest.

- Table 4. Pharmacokinetics of STM 434.

Table 6. Grade ≥ 3 Treatment Emergent Adverse Events in ≥ 2 patients.

- Table 3. Treatment Emergent Adverse Events (TEAEs) in ≥ 10% of subjects.