Genenta's Temferon™: Evidence of Controlled and Targeted Interferon Expression in Preliminary Phase I/II Clinical Data in Glioblastoma Multiforme

November 16, 2020

Data presented at 2020 Society for Neuro-Oncology (SNO) Annual Meeting

MILAN (Italy) / NEW YORK (NY, USA) — Genenta Science, a clinical-stage biotechnology company pioneering the development of hematopoietic stem progenitor cell immuno-gene therapy for cancer (Temferon™), presents new preliminary clinical data from a Phase I/IIa study of Temferon in patients affected by glioblastoma multiforme (GBM) at the 2020 Society for Neuro-Oncology (SNO) Annual Meeting, taking place November 19-22 in Austin, TX.

To date, ten patients were enrolled and eight were treated. Temferon was well tolerated, as suggested by the rapid hematological recovery and engraftment of modified cells observed in all the treated patients. No dose limiting toxicities were identified.

T-cell immunorepertoire changes were observed after treatment with evidence for clonal expansion, including tumor associated clones, suggesting a possible reset of T-cell responses, which are known to play a key role in the tumor-induced tolerance.

Interferon-alpha (IFN-α) response was identified across a number of tumor infiltrating myeloid cells while a low concentration of IFN-α was detected in the plasma and cerebrospinal fluid (CSF) of patients. This provides evidence that the Temferon built-in control mechanism is working to reduce the risk of IFN-α off-target effects preserving the desired in situ biological effects.

Pierluigi Paracchi, Chairman and Chief Executive Officer at Genenta Science, said: "These preliminary results are exciting indications of the feasibility, safety and local biological activity of our approach. The data are encouraging and in line with our pre-clinical results, with preliminary evidence of changes in the immune system and that Temferon is well tolerated without systemic toxicities."

Temferon-derived differentiated cells, as determined by vector copy number (VCN) in peripheral blood and bone marrow, were evident within 14 days of treatment and persist in peripheral blood in the long term (up to one year). Preliminary data on tumor specimens at second surgery confirmed the presence of TEMs and suggested that a higher IFN response gene signature may occur after treatment in stable lesions, compared to lesions that progress.