Cortice Biosciences Announces Presentation of Results from a Phase 1/2 Clinical Trial Evaluating TPI 287 for Treatment of Recurrent Glioblastoma at the 21st Annual Scientific Meeting of the Society of Neuro-Oncology

– Median overall survival improved to 13.4 from 12.9 months after extended follow-up –

– 64% of patients alive after one year compared to historical rates of 25-38% –

– Safety profile remains favorable; no dose-limiting toxicities to date –

SCOTTSDALE, AZ – November 18, 2016 – Cortice Biosciences announced today follow-up results from CB-017, a Phase 1/2 clinical trial evaluating TPI 287 plus bevacizumab (Avastin®) in patients with recurrent glioblastoma (GBM) who have not received prior bevacizumab. These results will be presented this evening during a poster session at the 21st Annual Scientific Meeting of the Society of Neuro-Oncology.

TPI 287 is a novel microtubule stabilizing agent that readily penetrates the blood-brain barrier. Prior preclinical and clinical results support the potential of this agent for the treatment of aggressive brain cancers in patients with few therapeutic options.

"Results from our TPI 287 development program continue to support meaningful drug activity in GBM," said George Farmer, Ph.D., Chief Executive Officer of Cortice. "Compared to overall survival rates observed in other multi-center clinical trials enrolling similar GBM populations, outcomes of CB-017 are very encouraging. We look forward to continued development of TPI 287 for treatment of GBM and presenting final results from the Phase 1 portion of CB-017 at another medical meeting next year."

Results in detail

Twenty-four patients with recurrent GBM that had progressed beyond first line treatment and who had not received prior bevacizumab were enrolled in the dose-escalation portion of CB-017. In addition to TPI 287 (140 to 220 mg/m2 administered every three weeks in seven dose cohorts), all patients received standard-of-care bevacizumab (10 mg/kg every two weeks). Twenty and 23 patients were evaluable for overall response and overall survival, respectively.

Key efficacy metrics are as follows:

- Overall response
    - As previously reported, 12 patients achieved an objective response per RANO criteria, including 3 complete (CR) and 9 partial (PR) responses. This corresponds to a 60% overall response rate.
    - Ten patients achieved stable disease (SD) and 1 patient had progressive disease at first assessment for response. This corresponds to a 96% disease control rate (CR + PR + SD).
- Survival
    - Final median progression free survival from this portion of the study is 5.5 months [95% C.I. 4.1, 8.2].
    - To date, median overall survival is 13.4 months [95% C.I. 10.9, 17.9] after the occurrence of 83% of possible events and a median follow-up of 24.7 months.
    - Of 22 patients with sufficient follow-up, 14 (64%) were or have been alive for at least 1 year.

Safety data available from 22 patients enrolled in CB-017 supports the favorable tolerability profile of TPI 287. With the exception of Grade 3 myelosuppression (3 patients), all adverse events regarded as possibly related to TPI 287 have been mild to moderate. No dose limiting toxicities (DLTs) have been observed to date.

Based on observations from CB-017 so far, an optimal dose of TPI 287 has been selected for the expansion stage of the trial. Following guidance provided by FDA, results from this study will inform the design of a single Phase 3 registration trial for TPI 287 in GBM.

"The improvement in median overall survival to 13.4 from 12.9 months appears to be driven by outcomes in patients treated at the higher doses of this study," said Dr. Samuel Goldlust, Medical Director of the Brain and Spine Institute of the John Theurer Cancer Center in Hackensack, NJ and Principal Investigator of CB-017. "This positive survival trend and the excellent tolerability of TPI 287 observed in the study to date support continued investigation in recurrent glioblastoma, an indication in desperate need of new therapies."

About TPI 287

TPI 287 is a novel taxoid which binds to and stabilizes the assembly of microtubules similarly to commonly used taxanes, including paclitaxel (Taxol® and Abraxane®) and docetaxel (Taxotere®). In oncology treatment settings, microtubule stabilization by these agents leads to mitotic arrest and cancer cell death. TPI 287 has advantages over these taxanes for the treatment of brain cancers due to its ability to penetrate the central nervous system, which is often shielded from systemic administration of other anti-cancer drugs. Microtubule stabilization by TPI 287 may also have potential for the treatment of neurologic disorders affected by tau protein pathology. These include tauopathies such as Alzheimer's disease and orphan diseases, such as progressive supranuclear palsy, corticobasal degeneration, and frontotemporal dementia.

About Glioblastoma

Glioblastoma (GBM) is the most aggressive and common form of brain cancer. Five-year survival after diagnosis is about 5%. The Central Brain Tumor Registry estimates that about 24,790 primary malignant brain tumors cases will be diagnosed in the US in 2016, 46% of which will be GBM. Typical front-line treatments include stereotactic or whole brain radiotherapy plus temozolomide (Temodar®). Patients with recurrent disease are candidates for treatment with Avastin®, the last drug approved by FDA for this disease.

About Cortice Biosciences

Cortice Biosciences, Inc. is a clinical-stage drug development company developing novel therapies for oncologic and neurologic disease indications with urgent unmet medical need. More information can be found at www.corticebiosciences.com.

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