NuCana Reports Preliminary Data from Phase II Study of Single-Agent Acelarin (NUC-1031) in Patients with Platinum-Resistant Ovarian Cancer

Confirmed Complete Response and Two Partial Responses Achieved in Heavily Pre-treated Population

Patients had Median of Five Prior Lines of Therapy

Edinburgh, United Kingdom, March 10, 2020 (GLOBE NEWSWIRE) – NuCana plc (NASDAQ: NCNA) announced preliminary results from part one of the Phase II study of single-agent Acelarin in patients with platinum-resistant ovarian cancer (PRO-105). This part of the study compared a 500mg/m² dose of Acelarin versus a 750mg/m² dose of Acelarin in patients who were heavily pre-treated (at least 3 prior lines of chemotherapy). This study is now closed to recruitment and data analysis from part one of the study is ongoing.

Forty-five patients with platinum-resistant ovarian cancer were evaluable for response and all responses had confirmatory scans. Based on an assessment by blinded independent central review, one patient achieved a complete response and two patients achieved partial responses. In addition, 16 patients achieved stable disease.

Patients who entered PRO-105 were heavily pre-treated, having received a median of five prior lines of treatment, and 72% had at least one comorbidity at study entry. Highlighting the fragility of this difficult-to-treat patient population, 45% of patients did not complete the first cycle of treatment with Acelarin despite not having any disease progression or any serious Grade 3 or 4 adverse events. However, for 23 patients in the study who received two or more cycles of Acelarin, the confirmed response rate was 13% and the disease control rate was 83%. These data are still being analyzed and the findings remain preliminary and subject to change.

NuCana’s CEO, Hugh S. Griffith, remarked: “We are pleased with this favorable disease control rate and Acelarin’s ability to achieve confirmed complete and partial responses in this very heavily pre-treated patient population. We are further encouraged by these results in light of the recent CLIO study in less heavily pre-treated patients with platinum-resistant ovarian cancer, where no patients in the chemotherapy group achieved a complete response and only one patient achieved a confirmed partial response which resulted in a confirmed overall response rate of 3%.”

The CLIO study reported on the efficacy of the current chemotherapy standards of care, namely paclitaxel, pegylated liposomal doxorubicin, topotecan and gemcitabine. Thirty-three patients received chemotherapy in the CLIO trial and were significantly less heavily pre-treated than those in the PRO-105 trial, with a median of 3 prior lines of treatment. However, given differences in trial design and statistical analyses, comparisons across studies should be interpreted with caution.

Part two of the PRO-105 study was designed to then investigate the optimal dose identified in part one in an expansion cohort. In December 2019, consistent with NuCana’s previous announcement that it is prioritizing resources on its key programs of Acelarin in biliary tract cancer and NUC-3373 in colorectal cancer, the Company determined not to proceed with part two of the PRO-105 study.

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Mr. Griffith concluded: “The advent of PARP inhibitors has changed the ovarian cancer treatment landscape markedly in recent years resulting in a more complex regulatory pathway for single-agent therapy. In addition, we have been very encouraged by the synergy we have observed with Acelarin in combination with platinum agents, both in patients with biliary tract cancer and ovarian cancer. As such, any further development of Acelarin in patients with ovarian cancer would likely involve combining it with a platinum agent.”

About NuCana plc

NuCana is a clinical-stage biopharmaceutical company focused on significantly improving treatment outcomes for cancer patients by applying our ProTide technology to transform some of the most widely prescribed chemotherapy agents, nucleoside analogs, into more effective and safer medicines. While these conventional agents remain part of the standard of care for the treatment of many solid and hematological tumors, their efficacy is limited by cancer cell resistance mechanisms and they are often poorly tolerated. Utilizing our proprietary technology, we are developing new medicines, ProTides, designed to overcome key cancer resistance mechanisms and generate much higher concentrations of anti-cancer metabolites in cancer cells. Our most advanced ProTide candidates, Acelarin and NUC-3373, are new chemical entities derived from the nucleoside analogs gemcitabine and 5-fluorouracil, respectively, two widely used chemotherapy agents. Acelarin is currently being evaluated in four clinical studies, including a Phase III study for patients with biliary tract cancer, a Phase Ib study for patients with biliary tract cancer, a Phase II study for patients with platinum-resistant ovarian cancer and a Phase III study for patients with metastatic pancreatic cancer for which enrollment has been suspended. NUC-3373 is currently in a Phase I study for the potential treatment of a wide range of advanced solid tumors and a Phase Ib study for patients with previously treated metastatic colorectal cancer. Our third ProTide, NUC-7738, is a transformation of a novel nucleoside analog (3’-deoxyadenosine) and is in a Phase I study for patients with advanced solid tumors.

Forward-Looking Statements

This press release may contain “forward-looking” statements within the meaning of the Private Securities Litigation Reform Act of 1995 that are based on the beliefs and assumptions and on information currently available to management of NuCana plc (the “Company”). All statements other than statements of historical fact contained in this press release are forward-looking statements, including statements concerning the Company’s planned and ongoing clinical studies for the Company’s product candidates and the potential advantages of those product candidates, including Acelarin, NUC-3373 and NUC-7738; the initiation, enrollment, timing, progress, release of data from and results of those planned and ongoing clinical studies; and the utility of prior non-clinical and clinical data in determining future clinical results. In some cases, you can identify forward-looking statements by terminology such as “may,” “will,” “should,” “expects,” “plans,” “anticipates,” “believes,” “estimates,” “predicts,” “potential” or “continue” or the negative of these terms or other comparable terminology. Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause the Company’s actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. These risks and uncertainties

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include, but are not limited to, the risks and uncertainties set forth in the “Risk Factors” section of the Company’s Annual Report on Form 20-F for the year ended December 31, 2018 filed with the Securities and Exchange Commission ("SEC") on March 7, 2019, and subsequent reports that the Company files with the SEC. Forward-looking statements represent the Company’s beliefs and assumptions only as of the date of this press release. Although the Company believes that the expectations reflected in the forward-looking statements are reasonable, it cannot guarantee future results, levels of activity, performance or achievements. Except as required by law, the Company assumes no obligation to publicly update any forward-looking statements for any reason after the date of this press release to conform any of the forward-looking statements to actual results or to changes in its expectations.

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