Edinburgh, U.K. 30th November 2020

Final Data from the Phase Ib Study of Acelarin plus Cisplatin in Patients with Advanced Biliary Tract Cancer Published Online Ahead of Print in The Oncologist

Acelarin plus Cisplatin's High Objective Response Rate and Favorable Safety Profile Confirmed

NuTide:121 Global Phase III Study Recruitment Ongoing

Edinburgh, United Kingdom, November 30, 2020 (GLOBE NEWSWIRE) – NuCana plc (NASDAQ: NCNA) announced that the final results of the Phase Ib study of Acelarin plus cisplatin for patients with advanced biliary tract cancer (ABC-08) have been published online ahead of print in The Oncologist. Encouraging interim data had previously been reported and the final data confirm the high objective response rate and favorable safety profile of Acelarin plus cisplatin in this patient population.

In the efficacy-evaluable patient population, the Objective Response Rate was 44%. By comparison, in the ABC-02 study, which led to gemcitabine plus cisplatin becoming the current standard of care for the first-line treatment of patients with advanced biliary tract cancer, an Objective Response Rate of 26% was achieved in the efficacy-evaluable population.

Dr. Mairéad McNamara, Co-Chief Investigator of the ABC-08 study and Senior Lecturer and Honorary Consultant in Medical Oncology at the University of Manchester and The Christie NHS Foundation Trust remarked: "Acelarin combined with cisplatin demonstrated a favorable safety profile and achieved good tumor control. Responses were seen across all five biliary tract cancer sub-types, including a Complete Response in one patient, a very rare occurrence in this patient population. In ABC-02, only one out of 161 efficacy-evaluable patients who received gemcitabine plus cisplatin achieved a Complete Response. Additionally, one patient with Stable Disease, whose tumor had initially been considered unsuitable for surgical resection, was able to have complete surgical removal of the tumor following treatment with Acelarin plus cisplatin. Four patients were still alive at the end of follow-up, having survived between 16 and 36 months."

"We are very encouraged by the final efficacy and safety data from ABC-08", said Hugh S. Griffith, NuCana's founder and CEO. "We are committed to developing Acelarin plus cisplatin as the first approved front-line treatment for patients with advanced biliary tract cancer. We continue to drive recruitment in the ongoing Phase III NuTide:121 Study where we believe we have the potential opportunity to apply for accelerated approval based on Objective Response Rate. We remain on track to enroll the required number of patients in NuTide:121 by the end of 2021 in order to conduct the first interim analysis in 2022."

Professor Juan Valle, Co-Chief Investigator of the ABC-02, ABC-08 and NuTide:121 studies and Professor and Honorary Consultant in Medical Oncology at the University of Manchester and The Christie NHS Foundation Trust said: "Biliary tract cancer is a devastating disease for which more effective treatments are desperately needed. While targeted therapies and immunotherapies may play a role in the treatment of biliary tract cancer in the future, chemotherapy will remain the backbone of treatment. Medicines like Acelarin, with the potential for improved efficacy and safety, would be welcome additions to the treatment options for patients with biliary tract cancer."

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About NuTide:121

NuTide:121 is a global, multi-center, randomized Phase III study that is enrolling up to 828 patients in approximately 130 sites across North America, Europe, Asia and Australia. Patients are being randomized 1:1 and treated with either a combination of Acelarin (725 mg/m^2) plus cisplatin (25 mg/m^2) or the current standard of care regimen, gemcitabine (1,000 mg/m^2) plus cisplatin (25 mg/m^2). The primary objectives of NuTide:121 are Overall Survival (OS) and Objective Response Rate (ORR). Three interim analyses, including two designed to support accelerated approval, are planned as part of the Phase III study protocol, in addition to the final analysis. Based on discussions with the FDA and subject to any further regulatory guidance, the Company believes that a statistically significant improvement in ORR at either of the first two interim analyses, supported by positive trends in other endpoints, could potentially allow for an accelerated approval of a new drug application (NDA) for Acelarin. Accelerated approval requires a confirmatory clinical study to verify the drug's clinical benefit. If accelerated approval were to occur, NuTide:121 would continue and the Company anticipates that data from subsequent analyses could provide the confirmatory data to support full (regular) approval.

About Biliary Tract Cancer

Biliary tract cancer, including cholangiocarcinoma, gallbladder and ampullary carcinoma, is cancer originating in the bile duct, a vessel that transports bile from the liver to the gallbladder and small intestine. Approximately 178,000 new cases of biliary tract cancer are diagnosed each year worldwide, with more than 18,000 of those diagnoses in the United States. There are currently no agents approved for the treatment of biliary tract cancer; however, the worldwide standard of care in the first-line setting for patients with advanced biliary tract cancer is the combination of gemcitabine and cisplatin.

About NuCana plc

NuCana is a clinical-stage biopharmaceutical company focused on significantly improving treatment outcomes for patients with cancer 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. NuCana's robust pipeline includes three ProTides in clinical development. 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 three clinical studies, including a Phase III study for patients with advanced 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 patients with advanced solid tumors and a Phase Ib study for patients with 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.

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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, including NuTide:121; the potential for accelerated approval of Acelarin; the Company's goals with respect to the development and potential use, if approved, of each of its product candidates; 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 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, 2019 filed with the Securities and Exchange Commission ("SEC") on March 10, 2020, 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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