NuCana Announces Promising Clinical Data at ASCO GI on NUC-1031 (Acelarin®) as Front-Line Treatment of Advanced Biliary Tract Cancer

NuCana Planning to Initiate a Phase III Study of Acelarin in Front-Line Advanced Biliary Tract Cancer

Edinburgh, United Kingdom, January 19, 2018 (GLOBE NEWSWIRE) – NuCana plc (NASDAQ: NCNA) announced interim results today from the ABC-08 Study at the 2018 ASCO Gastrointestinal Cancer Symposium (ASCO GI) in San Francisco, CA. This analysis of the Phase Ib multi-center, open-label study showed that Acelarin, when combined with cisplatin, achieved high response rates and was well-tolerated in front-line advanced biliary tract cancer.

Eight patients with advanced biliary tract cancer received Acelarin (625mg/m²) and cisplatin (25mg/m²) on days one and eight of a three-week cycle. A Complete Radiological Response was achieved in one patient, a Partial Response in three patients, and Stable Disease in one patient, resulting in an Objective Response Rate of 50% and a Disease Control Rate of 63% on an intent-to-treat basis. Additionally, the one patient with Stable Disease, whose cancer initially had been considered unsuitable for surgical resection, went on to have surgery to remove the tumor completely. Two of the eight patients received only one cycle or less of therapy due to complications unrelated to either Acelarin or cisplatin, so the Objective Response Rate in those patients who received adequate treatment was 67%.

“Although this is only an interim analysis in a small number of patients, these data are very encouraging and suggest that the combination of Acelarin and cisplatin could represent a significant advance in the treatment of advanced biliary tract cancer, a devastating disease for which there are no approved medicines,” remarked Professor Juan Valle, Co-Chief Investigator of the ABC-08 Study and Professor and Honorary Consultant in Medical Oncology at the University of Manchester and The Christie, Manchester, United Kingdom.

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, added, “In addition to the high response rate, it was noteworthy that this combination achieved a Complete Response and the patient with Stable Disease went on to have surgical resection. Both outcomes are very uncommon in this setting.”

Additionally, the combination of Acelarin and cisplatin was well-tolerated with no unexpected adverse events and no dose-limiting toxicities.

Based on the high response rates and favorable safety profile seen in cohort I, the Trial Management Group determined that Acelarin at 625mg/m² with cisplatin at 25mg/m² was the optimal combination. Professor Valle and his co-investigators had previously established the current standard of care for the front-line treatment of patients with advanced biliary tract cancer in the ABC-02 study that was published in the New England Journal of Medicine in 2010. Professor Valle added, “Since ABC-02, there have not been any studies that have demonstrated an improvement in overall survival in the front-line treatment of patients with advanced biliary tract cancer; there is an urgent need for new therapies for our patients.”

A comparison of the data from the ABC-08 and ABC-02 studies is provided in the following table:

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<th>ABC-08</th>
<th>ABC-022</th>
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<tbody>
<tr>
<td></td>
<td>NUC-1031 + cisplatin</td>
<td>gemcitabine + cisplatin</td>
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<tr>
<td></td>
<td>625mg/m² + 25mg/m²</td>
<td>1000mg/m² + 25mg/m²</td>
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<tr>
<td>Complete Response</td>
<td>13% (1/8)</td>
<td>0.6% (1/161)</td>
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<tr>
<td>Partial Response</td>
<td>38% (3/8)</td>
<td>25.5% (41/161)</td>
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<tr>
<td>Objective Response Rate</td>
<td>50% (4/8)</td>
<td>26.1% (42/161)</td>
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Hugh S. Griffith, NuCana’s Chief Executive Officer, said: “We are excited by the exceptional results achieved so early in this study. Consistent with our strategy of rapidly advancing our new medicines in multiple cancer types, and based on the results of this study, we plan to initiate a pivotal study of Acelarin and cisplatin in front-line advanced biliary tract cancer in 2018.”

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 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 three clinical studies for patients with ovarian cancer, biliary cancer and pancreatic cancer. NUC-3373 is currently in a Phase I study for the potential treatment of a wide range of advanced solid tumors.

For more information, please visit: www.nucana.com

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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 initiation, timing, progress and results of clinical studies of the Company’s product candidates. 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 our prospectus filed pursuant to Rule 424(b)(4) under the U.S. Securities Act of 1933, as amended, on September 29, 2017, and subsequent reports that we file with the U.S. Securities and Exchange Commission. 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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