

Edinburgh, U.K. 13<sup>th</sup> November 2019

## **NuCana Reports Third Quarter 2019 Financial Results and Provides Business Update**

***Opens Phase III Global Biliary Tract Cancer Study (NuTide:121) with Potential for Accelerated Approval Filing***

***Focusing Resources on Key Value-Driving Programs of Biliary Tract Cancer and Colorectal Cancer***

***Cash and Cash Equivalents to Fund Operations into the Second Half of 2021***

***Numerous Clinical Data Announcements and Study Initiations Expected in 2020***

Edinburgh, United Kingdom, November 13, 2019 (GLOBE NEWSWIRE) – NuCana plc (NASDAQ: NCNA) announced financial results for the third quarter ended September 30, 2019 and provided an update on its extensive clinical program with its transformative ProTide™ therapeutics.

As of September 30, 2019, NuCana had cash and cash equivalents of £58.1 million compared to £65.2 million as of June 30, 2019 and £77.0 million as of December 31, 2018. NuCana continues to advance its various clinical programs and reported a net loss of £3.9 million for the quarter ended September 30, 2019, as compared to £2.5 million for the quarter ended September 30, 2018. Basic and diluted loss per share was £0.12 for the quarter ended September 30, 2019, as compared to £0.08 per share for the quarter ended September 30, 2018.

“We are making excellent progress advancing our pipeline of novel ProTides,” said Hugh S. Griffith, NuCana’s Founder and Chief Executive Officer. “We recently announced that we have received FDA clearance of our IND and have commenced patient enrollment in NuTide:121, our global Phase III study comparing Acelarin plus cisplatin to gemcitabine plus cisplatin in patients with advanced biliary tract cancer. We are excited that NuTide:121 has the potential to support both accelerated as well as full approval filings and we look forward to expediting the recruitment of patients to this study.” NuTide:121 will enroll up to 828 patients in approximately 120 sites across North America, Europe, Asia and Australia. The primary objectives 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.

Mr. Griffith continued: “We are also excited about the potential of our other two ProTides in the clinic. We recently presented initial PK data from part one of NuTide:302, the Phase Ib study of NUC-3373 in combination with other agents typically combined with 5-FU in patients with advanced colorectal cancer. We believe NUC-3373 has significant commercial potential as more than 500,000 patients in North America are estimated to receive 5-FU each year. We also announced non-clinical data on NUC-7738, our ProTide transformation of a novel nucleoside analog, 3'-deoxyadenosine, detailing multiple potential anti-cancer modes of action.”

NuCana also announced that it is prioritizing resources on its two key programs: Acelarin in biliary tract cancer and NUC-3373 in colorectal cancer. Mr. Griffith remarked: “While our ProTides have the potential to become the new standard of care across multiple indications, we need to focus on programs that we believe will deliver the greatest clinical benefit to patients and create the most value for shareholders.

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In prior studies, Acelarin has generated positive data in patients with ovarian cancer, both as a single agent as well as in combination with carboplatin. We plan to announce data from the ongoing PRO-105 study of single-agent Acelarin in patients with platinum-resistant ovarian cancer in the first half of 2020. However, the advent of PARP inhibitors has changed the treatment landscape for patients with ovarian cancer resulting in a more complex regulatory pathway for single-agent therapy. We have been highly encouraged by the synergy we have observed with Acelarin in combination with platinum agents, both in patients with biliary tract cancer and ovarian cancer. Thus, should we elect to pursue further development of Acelarin in patients with ovarian cancer, we would anticipate combining it with a platinum agent.”

Based on this prioritization of resources, NuCana believes its current cash and cash equivalents will be sufficient to fund its planned operations into the second half of 2021 as compared to its previous expectation of into 2021. In addition to continuing or completing the ongoing clinical studies, NuCana expects its current cash and cash equivalents will enable the following:

- Continuing to run the Phase III study of Acelarin in combination with cisplatin in patients with biliary tract cancer;
- Initiating a Phase II/III study of NUC-3373 in combination with other agents for patients with colorectal cancer.

Mr. Griffith concluded: “We look forward to announcing more data throughout 2020. We have continued to validate our ProTide technology’s ability to transform some of the most widely prescribed chemotherapy agents into what we believe will be more efficacious and safer treatments. With multiple milestones expected across our pipeline, we anticipate a busy and productive 2020 for NuCana.”

### Anticipated Milestones

- Acelarin is NuCana’s ProTide transformation of gemcitabine. In 2020, NuCana expects to:
  - Provide an update on enrollment in the Phase III study of Acelarin combined with cisplatin as a first-line treatment for patients with advanced biliary tract cancer.
  - Report data from the ongoing Phase II study (PRO-105) of single-agent Acelarin for patients with platinum-resistant ovarian cancer.
  - Provide an update on the investigator-sponsored Phase III study (Acelarate) of Acelarin as a first-line treatment compared to gemcitabine for patients with metastatic pancreatic cancer, for which enrollment has been suspended.
- NUC-3373 is NuCana’s second ProTide in clinical development, a transformation of the active anti-cancer metabolite of 5-FU. In 2020, NuCana expects to:
  - Report data from the ongoing Phase Ib study (NuTide:302) of NUC-3373 in patients with advanced colorectal cancer and establish the recommended Phase II dose of NUC-3373 in combination with other agents with which 5-FU is typically combined, including leucovorin oxaliplatin and irinotecan.
  - Contingent on regulatory guidance and other factors, initiate a Phase II/III study of NUC-3373 in combination with other agents for patients with colorectal cancer.
  - Report data from the ongoing Phase I study (NuTide:301) of NUC-3373 in patients with advanced solid tumors.

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- NUC-7738 is NuCana's ProTide transformation of a novel nucleoside analog, 3'-deoxyadenosine. In 2020, NuCana expects to:
  - Report data from the Phase I study (NuTide:701) of NUC-7738 in patients with advanced solid tumors.

### **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 gall bladder 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 biliary tract cancer patients with locally advanced or metastatic disease is the combination of gemcitabine and cisplatin. Patients receiving this regimen have a median overall survival of 11.7 months.

### **About Colorectal Cancer**

Colorectal cancer is a cancer that starts in the colon or the rectum. In the United States, approximately 145,000 new cases of colorectal cancer and 51,000 deaths due to the disease are expected in 2019. Worldwide, there were over 1.8 million new colorectal cancer cases in 2018, and the global burden is expected to increase to more than 2.2 million new cases and 1.1 million deaths annually by 2030. Most systemic therapies for colorectal cancer include 5-FU, typically in combination with other therapeutic agents such as oxaliplatin or irinotecan. 5-FU remains the single most prescribed compound for the treatment of colorectal cancer.

### **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 advanced 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 amount and sufficiency of the Company's current cash and cash equivalents to fund its planned operations into the second half of 2021, 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; 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, 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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## Unaudited Condensed Consolidated Statements of Operations

	For the three months ended		For the nine months ended	
	September 30, 2019	2018	September 30, 2019	2018
	<i>(in thousands, except per share data)</i>			
	<i>(unaudited)</i>			
	£	£	£	£
Research and development expenses	(4,845)	(3,333)	(14,551)	(12,196)
Administrative expenses	(1,423)	(957)	(4,231)	(3,599)
Net foreign exchange gains	1,227	706	1,191	1,765
<b>Operating loss</b>	<b>(5,041)</b>	<b>(3,584)</b>	<b>(17,591)</b>	<b>(14,030)</b>
Finance income	252	297	867	739
<b>Loss before tax</b>	<b>(4,789)</b>	<b>(3,287)</b>	<b>(16,724)</b>	<b>(13,291)</b>
Income tax credit	912	771	3,020	3,063
<b>Loss for the period</b>	<b>(3,877)</b>	<b>(2,516)</b>	<b>(13,704)</b>	<b>(10,228)</b>
Basic and diluted loss per share	(0.12)	(0.08)	(0.42)	(0.32)

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## Unaudited Condensed Consolidated Statements of Financial Position

	September 30, 2019	December 31, 2018
	<i>(in thousands)</i> <i>(unaudited)</i>	
	£	£
<b>Assets</b>		
<b>Non-current assets</b>		
Intangible assets	3,838	3,122
Property, plant and equipment	795	427
Deferred tax asset	28	47
	<b>4,661</b>	<b>3,596</b>
<b>Current assets</b>		
Prepayments, accrued income and other receivables	5,907	2,354
Current income tax receivable	7,284	4,263
Cash and cash equivalents	58,091	76,972
	<b>71,282</b>	<b>83,589</b>
<b>Total assets</b>	<b>75,943</b>	<b>87,185</b>
<b>Equity and liabilities</b>		
<b>Capital and reserves</b>		
Share capital and share premium	80,832	80,715
Other reserves	61,722	59,692
Accumulated deficit	(72,347)	(58,813)
<b>Total equity attributable to equity holders of the Company</b>	<b>70,207</b>	<b>81,594</b>
<b>Non-current liabilities</b>		
Provisions	26	26
Lease liability	247	-
	<b>273</b>	<b>26</b>
<b>Current liabilities</b>		
Trade payables	2,155	2,455
Payroll taxes and social security	136	127
Lease liability	190	-
Accrued expenditure	2,982	2,983
	<b>5,463</b>	<b>5,565</b>
<b>Total liabilities</b>	<b>5,736</b>	<b>5,591</b>
<b>Total equity and liabilities</b>	<b>75,943</b>	<b>87,185</b>

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## Unaudited Condensed Consolidated Statements of Cash Flows

	For the nine months ended September 30,	
	2019	2018
	<i>(in thousands)</i>	
	<i>(unaudited)</i>	
	£	£
<b>Cash flows from operating activities</b>		
Loss for the period	(13,704)	(10,228)
Adjustments for:		
Income tax credit	(3,020)	(3,063)
Amortization and depreciation	522	261
Finance income	(867)	(739)
Share-based payments	2,191	1,494
Net foreign exchange gains	(1,228)	(1,808)
	<b>(16,106)</b>	<b>(14,083)</b>
Movements in working capital:		
Increase in prepayments, accrued income and other receivables	(3,593)	(2)
(Decrease) increase in trade payables	(300)	1,416
Increase in payroll taxes, social security and accrued expenditure	8	878
Movements in working capital	<b>(3,885)</b>	<b>2,292</b>
<b>Cash used in operations</b>	<b>(19,991)</b>	<b>(11,791)</b>
Net income tax received	20	1,905
<b>Net cash used in operating activities</b>	<b>(19,971)</b>	<b>(9,886)</b>
<b>Cash flows from investing activities</b>		
Interest received	915	694
Payments for property, plant and equipment	(29)	(205)
Payments for intangible assets	(988)	(928)
<b>Net cash used in investing activities</b>	<b>(102)</b>	<b>(439)</b>
<b>Cash flows from financing activities</b>		
Payments for lease liabilities	(146)	-
Proceeds from issue of share capital	117	182
<b>Net cash (used in) from financing activities</b>	<b>(29)</b>	<b>182</b>
Net decrease in cash and cash equivalents	(20,102)	(10,143)
<b>Cash and cash equivalents at beginning of period</b>	<b>76,972</b>	<b>86,703</b>
Effect of exchange rate changes on cash and cash equivalents	1,221	1,791
<b>Cash and cash equivalents at end of period</b>	<b>58,091</b>	<b>78,351</b>

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