



BeyondSpring Provides Operational Update and Second-Quarter 2019 Financial Results

September 18, 2019

- To Submit New Drug Applications (“NDAs”) in China for Both Non-Small Cell Lung Cancer (“NSCLC”) and Chemotherapy-Induced Neutropenia (“CIN”) in Q1 2020 -

- To Submit NDAs in the United States (“U.S.”) for Both NSCLC and CIN in 2020 -

NEW YORK, Sept. 18, 2019 (GLOBE NEWSWIRE) -- [BeyondSpring Inc.](#) (“BeyondSpring” or the “Company”) (NASDAQ:BYSI), a global biopharmaceutical company focused on developing transforming immuno-oncology cancer therapies, today announced its financial results for the three months ended June 30, 2019, and provided an update on its operations.

“During the second quarter, we continued to demonstrate Plinabulin’s favorable drug profile for the treatment of NSCLC and CIN,” said Lan Huang, Ph.D., Chairman, Chief Executive Officer and Co-Founder of BeyondSpring. “In addition to results from our CIN studies, which provided strong rationale for the use of Plinabulin alone and in combination with G-CSF for the prevention of intermediate-risk and high-risk CIN, the Data Safety Monitoring Board advised Study 103 to continue after the first interim analysis.”

“In the near term, we expect to continue to generate additional data for Plinabulin in both NSCLC and CIN indications to support NDA filings in China followed by the U.S. Our recent financing activities position us well to achieve these key milestones,” added Dr. Huang.

Select Second-Quarter 2019 and Recent Highlights

NSCLC

Study 103

In September 2019, BeyondSpring announced that a poster describing the Company’s novel design for Study 103, titled “DUBLIN-3, a Phase (Ph) III Trial Comparing the Plinabulin (P) / Docetaxel (D) Combination with D Alone in Stage IIIB / IV NSCLC,” was presented at the International Association for the Study of Lung Cancer World Conference on Lung Cancer in Barcelona, Spain.

CIN

Study 105 (Intermediate-Risk Chemotherapy)

In August 2019, BeyondSpring announced that an abstract, titled “Quality of Life (QoL) in Advanced NSCLC Patients Treated with Docetaxel and with Either Plinabulin or Pegfilgrastim for the Prevention of Neutropenia,” was accepted for presentation at the September 8, 2019IASLC World Conference on Lung Cancer. The abstract demonstrates that, compared to Neulasta®, Plinabulin at 20mg/m² significantly improves QoL over four treatment cycles. Plinabulin also significantly improved fatigue, pain and insomnia.

At the International Society for Pharmacoeconomics and Outcomes Research 2019 Conference in May 2019, Dr. Douglas Blayney, global Principal Investigator for BeyondSpring’s CIN development program and Professor of Medicine at Stanford University Medical Center, presented data derived from the Phase 2 portion of Study 105 demonstrating that Plinabulin at 20mg/m² has a similar efficacy profile in reducing docetaxel-induced neutropenia as Neulasta 6mg, while avoiding the patient-reported bone pain typically observed with Neulasta.

Study 106 (High-Risk Chemotherapy)

In June 2019, BeyondSpring announced that two abstracts were accepted for publication in the Proceedings of the 2019 ASCO Annual Meeting. The data, derived from the Phase 2 portion of Study 106, provided a strong rationale for the Plinabulin-G-CSF combination for the prevention of CIN for improved CIN control. Additionally, the Plinabulin-G-CSF combination nearly eliminated patients’ treatment-related bone pain.

BeyondSpring is currently initiating the Phase 3 portion of Study 106.

Mechanism of Action

In April 2019, BeyondSpring presented novel data relevant to predictive biomarkers for patient selection for Plinabulin at the American Association for Cancer Research Annual Meeting. At the same conference, BeyondSpring presented preclinical data demonstrating Plinabulin’s ability to reduce tumor associated M2 macrophages, which are thought to support tumor cell survival and metastasis; as well as shift the phenotypic balance to one favoring M1 macrophages, which are thought to have anti-cancer properties.

Equity Financings

On July 19, 2019, BeyondSpring closed a public offering, led by Decheng Capital, of 2,058,825 ordinary shares at a public offering price of \$17.00 per share. Gross proceeds from the public offering were \$35.0 million before deducting underwriting discounts and commissions and other offering expenses. The Company intends to use the net proceeds of this offering to support continued clinical and pre-clinical development and for general corporate purposes.

In June and July 2019, BeyondSpring’s partially owned Chinese subsidiary, Dalian Wanchunbulin Pharmaceuticals Ltd. (“Wanchunbulin”) entered into definitive agreements for the sale of its equity interests (“Equity Purchase Agreements”) to certain investors led by Efung Capital. Under the Equity Purchase Agreements, Wanchunbulin expects to sell 4.76% of the equity of Wanchunbulin for aggregate cash consideration of RMB 100 million, or

approximately \$14.5 million, before deducting offering expenses, to finance clinical and pre-clinical development and for general corporate purposes. To date, the Company has received RMB 70 million, or approximately \$10.1 million, from this equity financing.

In May 2019, BeyondSpring entered into an Open Market Sale AgreementSM with Jefferies LLC to sell ordinary shares of the Company, with aggregate gross proceeds of up to \$30.0 million, from time to time, through an at-the-market ("ATM") facility. In July 2019, this facility was suspended in anticipation of the public offering completed on July 19, 2019. As at the ATM's suspension date, the Company had received aggregate gross proceeds of \$13.0 million on 620,753 ordinary shares already sold through this facility.

Financial Results for the Three Months Ended June 30, 2019

Research and development ("R&D") expenses were \$5.2 million for the quarter ended June 30, 2019, compared to \$11.0 million for the quarter ended June 30, 2018. The \$5.8 million decrease in R&D expenses was largely attributable to a \$3.9 million decrease in expense incurred by clinical research organizations and other service fee related to clinical trials, a \$1.1 million decrease in manufacturing expenses and a \$0.8 million decrease in non-cash share-based compensation.

General and administrative ("G&A") expenses were \$2.1 million for the quarter ended June 30, 2019, compared to \$1.4 million for the quarter ended June 30, 2018. The \$0.7 million increase in G&A expenses was mainly due to non-cash share-based compensation.

Net loss attributable to the Company was \$7.4 million for the quarter ended June 30, 2019, compared to \$12.2 million for the quarter ended June 30, 2018.

As of June 30, 2019, the Company has a cash balance of \$0.7 million. With the net proceeds received from the recent equity financing activities described above, the Company believes it has sufficient cash to support its clinical trials and submit NDAs in China for Plinabulin for the treatment of CIN and NSCLC, and to advance its immuno-oncology pipeline and its ubiquitination protein degradation research platform.

Anticipated Milestones

The following outlines the Company's key anticipated upcoming milestones and projected timelines.

- Second interim analysis for Study 103 Phase 3 for NSCLC – Q4 2019 / Q1 2020
- Final data readout for Study 105 Phase 3 for CIN – Q1 2020
- Top line data readout for Study 106 Phase 3 for CIN – Q1 2020
- Submit NDAs to China's National Medical Products Administration for Plinabulin for NSCLC and CIN – Q1 2020
- Submit NDAs to the FDA for Plinabulin for NSCLC and CIN – 2020

Conference Call and Webcast Information

BeyondSpring's management will host a conference call and webcast today at 8:00 a.m. Eastern Time to discuss the financial results and provide a corporate update. The dial-in numbers for the conference call are 1-877-451-6152 (U.S.) or 1-201-389-0879 (international). Please reference conference ID 13694411. A live webcast will be available on BeyondSpring's website at www.beyondspringpharma.com under "[Events & Presentations](#)" in the Investors section. An archived replay of the webcast will be available for 30 days.

About BeyondSpring

BeyondSpring is a global biopharmaceutical company focused on developing transforming immuno-oncology cancer therapies. BeyondSpring's lead asset, Plinabulin, is in two Phase 3 global clinical programs, one as a direct anticancer agent in the treatment of non-small cell lung cancer (NSCLC) and the other in the prevention of chemotherapy-induced neutropenia (CIN). BeyondSpring has strong R&D capabilities with a robust pipeline in addition to Plinabulin, including three immuno-oncology assets and a drug discovery platform using the ubiquitination degradation pathway. The Company also has a seasoned management team with many years of experience bringing drugs to the global market.

Cautionary Note Regarding Forward-Looking Statements

This press release includes forward-looking statements that are not historical facts. Words such as "will," "expect," "anticipate," "plan," "believe," "design," "may," "future," "estimate," "predict," "potential," "suggest," "objective," "goal," or variations thereof and variations of such words and similar expressions are intended to identify such forward-looking statements. Specifically, these forward-looking statements include, but are not limited to, statements relating to the Company's ability to establish its lead asset, Plinabulin, as a potentially superior new therapy for the treatment of chemotherapy-induced neutropenia and ability to advance its Phase 3 non-small cell lung cancer trial and earlier-stage programs, the potential for development and marketing of its product candidates, ability to advance its pipeline of immuno-oncology therapies and research activities, the potential effectiveness of Plinabulin, the potential for Plinabulin to address limitations in the current standard of care, the timing of clinical trials, receipt of clinical data or regulatory filings of the Company's product candidates, and the Company's ability to continue as a going concern. Forward-looking statements are based on BeyondSpring's current knowledge and its present beliefs and expectations regarding possible future events and are subject to risks, uncertainties and assumptions. Actual results and the timing of events could differ materially from those anticipated in these forward-looking statements as a result of several factors including, but not limited to, the anticipated amount needed to finance the Company's future operations, unexpected results of clinical trials, delays or denial in regulatory approval process, its expectations regarding the potential safety, efficacy or clinical utility of its product candidates, or additional competition in the market, and other risk factors referred to in BeyondSpring's current Form 20-F on file with the U.S. Securities and Exchange Commission. The forward-looking statements made herein speak only as of the date of this release and BeyondSpring undertakes no obligation to update publicly such forward-looking statements to reflect subsequent events or circumstances, except as otherwise required by law.

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BEYONDSRING INC.
AUDITED CONSOLIDATED BALANCE SHEET AS OF DECEMBER 31, 2018 AND
UNAUDITED INTERIM CONDENSED CONSOLIDATED BALANCE SHEET AS OF JUNE 30, 2019
(Amounts in thousands of U.S. Dollars (“\$”), except for number of shares and per share data)

	December 31, 2018	June 30, 2019
	\$	\$
		(Unaudited)
Assets		
Current assets:		
Cash	3,889	674
Advances to suppliers	1,209	1,123
Due from related parties	481	-
Prepaid expenses and other current assets	292	167
Total current assets	<u>5,871</u>	<u>1,964</u>
Noncurrent assets:		
Property and equipment, net	282	237
Operating lease right-of-use assets	-	2,855
Other noncurrent asset	910	958
Total noncurrent assets	<u>1,192</u>	<u>4,050</u>
Total assets	<u><u>7,063</u></u>	<u><u>6,014</u></u>
Liabilities and equity		
Current liabilities:		
Accounts payable	9,586	8,456
Accrued expenses	5,495	6,084
Due to related parties	-	1,375
Current portion of operating lease liabilities	-	535
Other current liabilities	1,364	2,469
Total current liabilities	<u>16,445</u>	<u>18,919</u>
Noncurrent liabilities:		
Long-term loans	-	2,913
Operating lease liabilities	-	2,264

Total noncurrent liabilities	-	5,177
Total liabilities	<u>16,445</u>	<u>24,096</u>
Deficit:		
Ordinary shares (\$0.0001 par value; 500,000,000 shares authorized; 23,184,612 and 23,594,480 shares issued and outstanding as of December 31, 2018 and June 30, 2019, respectively)	2	2
Additional paid-in capital	170,950	177,088
Accumulated deficit	(178,760)	(193,405)
Accumulated other comprehensive income	<u>42</u>	<u>76</u>
Total BeyondSpring Inc.'s shareholder's deficit	(7,766)	(16,239)
Noncontrolling interests	<u>(1,616)</u>	<u>(1,843)</u>
Total deficit	<u>(9,382)</u>	<u>(18,082)</u>
Total liabilities and deficit	<u><u>7,063</u></u>	<u><u>6,014</u></u>

BEYONDSRING INC.
UNAUDITED INTERIM CONDENSED CONSOLIDATED STATEMENTS OF
COMPREHENSIVE LOSS FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2018 AND 2019
(Amounts in thousands of U.S. Dollars ("\$\$"), except for number of shares and per share data)
(Unaudited)

	Three months ended		Six months ended	
	June 30,		June 30,	
	2018	2019	2018	2019
	\$	\$	\$	\$
Revenue	-	-	-	-
Operating expenses				
Research and development	(10,994)	(5,202)	(25,068)	(11,532)
General and administrative	<u>(1,388)</u>	<u>(2,147)</u>	<u>(2,116)</u>	<u>(3,786)</u>
Loss from operations	(12,382)	(7,349)	(27,184)	(15,318)
Foreign exchange gain (loss), net	(460)	(169)	(128)	4
Interest expense	-	(103)	-	(140)
Interest income	55	1	128	7
Other income	<u>-</u>	<u>-</u>	<u>316</u>	<u>-</u>
Loss before income tax	(12,787)	(7,620)	(26,868)	(15,447)
Income tax benefit	<u>-</u>	<u>-</u>	<u>-</u>	<u>-</u>
Net loss	(12,787)	(7,620)	(26,868)	(15,447)
Less: Net loss attributable to noncontrolling interests	(621)	(268)	(1,046)	(802)
Net loss attributable to BeyondSpring Inc.	<u><u>(12,166)</u></u>	<u><u>(7,352)</u></u>	<u><u>(25,822)</u></u>	<u><u>(14,645)</u></u>
Net loss per share				
Basic and diluted	<u>(0.54)</u>	<u>(0.32)</u>	<u>(1.16)</u>	<u>(0.64)</u>
Weighted-average shares outstanding				

Basic and diluted	<u>22,397,442</u>	<u>23,094,161</u>	<u>22,342,822</u>	<u>23,061,941</u>
Other comprehensive loss, net of tax of nil:				
Foreign currency translation adjustment gain	<u>169</u>	<u>225</u>	<u>104</u>	<u>31</u>
Comprehensive loss	<u>(12,618)</u>	<u>(7,395)</u>	<u>(26,764)</u>	<u>(15,416)</u>
Less: Comprehensive loss attributable to noncontrolling interests	<u>(630)</u>	<u>(230)</u>	<u>(1,024)</u>	<u>(805)</u>
Comprehensive loss attributable to BeyondSpring Inc.	<u>(11,988)</u>	<u>(7,165)</u>	<u>(25,740)</u>	<u>(14,611)</u>

Source: BeyondSpring, Inc.