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NEWS RELEASE

Agenus Reports Third Quarter 2023 Results

11/7/2023

Conference Call on Tuesday, November 7, 2023, at 9:00 a.m. ET

LEXINGTON, Mass.--(BUSINESS WIRE)-- Agenus Inc. (“Agenus”) (Nasdaq: AGEN), a leader in discovering and developing novel immunological agents to treat various cancers, today announced results for the third quarter 2023. Agenus executives will host a conference call and webcast at 9:00 a.m. ET to discuss the results and to provide a corporate update.

Key highlights include:

- Recent data shows that botensilimab (BOT), with or without balstilimab (BAL), is broadly effective in treating five advanced solid tumors: colorectal, pancreatic, lung, melanoma, and sarcoma.
- Over the past 12 months, clinical data on BOT/BAL has been featured in six oral or plenary sessions at major cancer conferences and published in peer-reviewed medical and scientific journals.
- Considering the poor treatment alternatives for patients with advanced colorectal cancer (CRC) and the promising, long-lasting benefits of BOT/BAL, a Biologics License Application (BLA) is anticipated for submission to the U.S. Food & Drug Administration (FDA) for microsatellite stable (MSS) metastatic CRC in mid-2024.
- Enrollment for the ACTIVATE-CRC Phase 2 Trial is complete; data readouts for the ACTIVATE-Pancreatic, ACTIVATE-Melanoma, and the Phase 1b trial in non-small cell lung cancer (NSCLC) are expected throughout 2024.

"The botensilimab franchise, after treating more than 750 patients, has demonstrated consistent tumor responses across a diverse range of nine tumor types, showcasing its potential for significant impact in oncology," said Chief Executive Officer, Garo Armen, Ph.D. "The emerging data indicating the efficacy of botensilimab in earlier stages of cancer marks a notable shift towards less invasive treatment options. Agenus is forging ahead with a focus on our regulatory filing in CRC, advancing our robust clinical pipeline, and committing to deliver substantial outcomes for

patients and create value for our shareholders."

New and Updated Botensilimab Data at Corporate Event During ESMO 2023

Microsatellite Stable Colorectal Cancer (MSS CRC) Patients:

- In an analysis of 70 patients evaluable for efficacy, those without active liver metastases exhibited a confirmed response rate (ORR) of 24%, significantly surpassing the 2.8% achieved with standard of care (SOC). [1]
- These patients demonstrated a 12-month overall survival (OS) rate of 74%, with median OS not yet reached, compared to a 12.9-month benchmark with [1], with a median follow-up of 12.3 months.

Based on the totality of the evidence from the Phase 1 and Phase 2 trials, Agenus plans to submit its BLA to the U.S. FDA for BOT/BAL in patients with 2/3L+ MSS CRC in mid-2024 and an EU marketing authorization filing in 2025. Interactions with regulatory agencies are ongoing.

Neoadjuvant CRC*:

- Treatment with one dose of BOT and two doses of BAL resulted in considerable tumor size reduction within approximately four weeks prior to surgery.
- All three patients with MSI-H CRC experienced major pathological responses (>90%), while 67% (6/9) of MSS CRC patients who don't normally respond to other Immuno-oncology (IO) treatments, had responses 50% or greater, including two complete responses.
- Agenus plans to prioritize neoadjuvant development and is evaluating study designs for potential registration.

2L Metastatic Pancreatic:

- In FOLFIRINOX relapsed/refractory (2L) metastatic pancreatic cancer patients, all of whom had liver metastases, 4 of 6 experienced marked tumor marker reductions associated with ongoing tumor reductions when treated with gemcitabine-Abraxane in combination with botensilimab.
- A Phase 2 randomized study is in progress, with an update expected in the first half of 2024 and a possible supplemental BLA filing in 2025.

2L+ CTLA-4/PD-1 Relapsed Refractory Advanced Melanoma:

- Phase 1b expansion cohort in advanced melanoma reported a 30% ORR and 60% disease control rate; all patients had failed anti-PD-1 therapy and 8/10 had failed both anti-PD-1/CTLA-4 therapy.
- The Phase 2 results are expected in the second half of 2024, with the BOT monotherapy arm fully enrolled, and approximately 30 patients in the BOT/BAL combination arm. We are currently defining strategies for the rapid enrollment of BOT in melanoma patients who are refractory to current IO treatments and expect to pursue rapid registration strategies in 2024.

Refractory NSCLC:

- In the PD(L)-1 refractory cohort, a 56% ORR and an 89% disease control rate were observed in patients treated with the BOT/BAL combination (n=9).
- In the EGFR mutation refractory cohort, two objective responses were observed with one patient experiencing a -90% tumor reduction at 12 weeks.
- Phase 1b results are expected in mid-2024, with approximately 50 patients enrolled. With the data generated, we are in the process of designing trials to support rapid approval in patients that are refractory to PD-1, as well as cohorts of patients with mutations, who have no viable treatment options.

Advanced Sarcomas:

- Updated findings from a Phase 1b study of 41 efficacy evaluable patients presented at ESMO 2023 showed

continued efficacy, with an ORR of 20%, a median response duration of 19.4 months (iRECIST), and a 6-month progression-free survival rate of 40%.

- A higher ORR was observed by dose level, with 29% at 2 mg/kg BOT compared to 15% at 1 mg/kg BOT.

Corporate Partnership Progress:

BMS-986442 (AGEN1777) – An Fc-Enhanced TIGIT Bispecific:

Bristol Myers Squibb's BMS-986442, originally developed by Agenus and known as AGEN1777, is a bispecific antagonist targeting both TIGIT and CD96. This therapeutic is designed to augment tumor-reactive T cell activity through its Fc-enhanced region. Following the licensing agreement in 2021, the phase 1 study in solid tumors concluded successfully. Currently, a phase 2 dose expansion study is underway, assessing BMS-986442 in combination with nivolumab, with or without chemotherapy. The screening for this phase commenced on October 13, 2023, and dosing of the first phase 2 patient is scheduled for November, which will result in a milestone payment for Agenus.

Third Quarter 2023 Financial Overview:

Given the current environment in the biotech sector and our financial resource needs to drive our objectives, we have taken and will continue to take steps to contain our costs. We are actively pursuing immediate prospects for additional cash infusion that don't involve stock issuances, including a milestone payment from one of our partnered programs, expected by the end of 2023. In addition to this expected milestone, we are in the process of selling two non-strategic assets and the partial sale of other milestones and royalties due to Agenus from our partnered programs. These three sales are expected to close by the end of the first half of 2024. With our end of third quarter cash, cash equivalent, and short-term investment balance of $106.3 million, along with these four planned transactions, we believe we are sufficiently funded through the end of 2024. In addition to these planned transactions, we are also in advanced discussions for a potential structured financing for BOT/BAL as well as a potential corporate collaboration with a large pharma or biotech company.

The third quarter 2023 closed with a consolidated cash, cash equivalent and short-term investment balance of $106.3 million, compared to $193.4 million at on December 31, 2022.

For the three and nine months ended September 30, 2023, we recognized revenue, which includes non-cash revenue, of $24.3 million and $72.5 million, respectively. Including non-cash expenses of $28.1 million, we incurred a net loss of $64.5 million for the third quarter. For the nine months of 2023, we incurred a net loss of $208.9 million including non-cash expenses of $82 million.

Select Financial Information
(in thousands, except per share data)
(unaudited)

	September 30, 2023	December 31, 2022
Cash, cash equivalents and short-term investments	$ 106,305	$ 193,358

	Three months ended September 30,		Nine months ended September 30,	
	2023	2022	2023	2022
Revenues, royalty sales milestone	$ -	$ 7,934	$ -	$ 25,250
Revenues, non-cash royalty	20,360	9,224	61,534	27,001
Revenues, research and development	3,414	4,573	8,515	13,220
Revenues, other	540	1,041	2,464	4,167
Total Revenue	24,314	22,772	72,513	69,638
Research and development expenses	51,443	46,011	167,846	133,412
General and administrative expenses	18,909	18,105	57,562	55,971
Cost of service revenue	303	308	2,851	2,875
Other income	(866)	(971)	(2,470)	(9,745)
Non-cash interest expense	19,057	16,041	55,977	44,629
Non-cash contingent consideration fair value adjustment	-	(7)	(398)	(950)
Net loss*	$ (64,532)	$ (56,715)	$ (208,855)	$ (156,554)
Net loss per share attributable to Agenus Inc. common stockholders	$ (0.16)	$ (0.19)	$ (0.57)	$ (0.54)

Conference Call

To access dial-in numbers, please register **here**.

Conference ID: 73242

Webcast

A live webcast and replay of the conference call will be accessible from the Events & Presentations page of the Company's website at **https://investor.agenusbio.com/events-and-presentations/** and via **https://events.q4inc.com/attendee/357374738**.

References

1. Cohen et al. ASCO Annual Meeting 2023

*Investigator Sponsored Trial (IST)

About Botensilimab

Botensilimab is an investigational multifunctional anti-CTLA-4 immune activator (antibody) designed to boost both innate and adaptive anti-tumor immune responses. Its novel design leverages mechanisms of action to extend immunotherapy benefits to "cold" tumors which generally respond poorly to standard of care or are refractory to conventional PD-1/CTLA-4 therapies and investigational therapies. Botensilimab augments immune responses across a wide range of tumor types by priming and activating T cells, downregulating intratumoral regulatory T cells, activating myeloid cells and inducing long-term memory responses.

Approximately 750 patients have been treated with botensilimab in phase 1 and phase 2 clinical trials. Botensilimab alone, or in combination with Agenus' investigational PD-1 antibody, balstilimab, has shown clinical responses across nine metastatic, late-line cancers. For more information about botensilimab trials, visit **www.clinicaltrials.gov** with the identifiers NCT03860272, NCT05608044, NCT05630183, and NCT05529316.

About Agenus

Agenus is a leading immuno-oncology company targeting cancer and infectious diseases with a comprehensive pipeline of immunological agents. The company's mission is to expand patient populations benefiting from cancer immunotherapy through combination approaches, using a broad repertoire of antibody therapeutics, adoptive cell therapies (through MiNK Therapeutics) and adjuvants (through SaponiQx). Agenus is headquartered in Lexington,

MA. For more information, visit **www.agenusbio.com** or **@agenus_bio**. Information that may be important to investors will be routinely posted on our website and social media channels.

Forward-Looking Statements

This press release contains forward-looking statements that are made pursuant to the safe harbor provisions of the federal securities laws, including statements regarding a its botensilimab and balstilimab programs, expected regulatory timelines and filings, and any other statements containing the words "may," "believes," "expects," "anticipates," "hopes," "intends," "plans," "forecasts," "estimates," "will," “establish,” “potential,” “superiority,” “best in class,” and similar expressions are intended to identify forward-looking statements. These forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially. These risks and uncertainties include, among others, the factors described under the Risk Factors section of our most recent Annual Report on Form 10-K for 2022, and subsequent Quarterly Reports on Form 10-Q filed with the Securities and Exchange Commission. Agenus cautions investors not to place considerable reliance on the forward-looking statements contained in this release. These statements speak only as of the date of this press release, and Agenus undertakes no obligation to update or revise the statements, other than to the extent required by law. All forward-looking statements are expressly qualified in their entirety by this cautionary statement.

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