

France Grants Reimbursed Compassionate Access (AAC) for Agenus' BOT/BAL in Refractory MSS Metastatic Colorectal Cancer

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LEXINGTON, Mass.--(BUSINESS WIRE)-- Agenus Inc. (Nasdaq: AGEN), a leader in immuno-oncology, today announced its investigational combination botensilimab plus balstilimab (BOT/BAL) is now available to eligible patients with refractory microsatellite-stable (MSS) metastatic colorectal cancer (mCRC) under France's compassionate access (Accès compassionnel, or AAC) framework. The French National Agency of Medicines and Health Products Safety's (ANSM) listings for botensilimab and balstilimab are live and detail eligibility (including MSS and no active liver metastases) and dosing. BOT/BAL remains investigational and is not approved for commercial marketing in France or elsewhere.

How AAC reimbursement works

Once the ANSM authorizes AAC, hospital use is covered 100% by Assurance Maladie. Hospitals are reimbursed at the invoiced purchase price (TTC), outside the Diagnosis-related Group (DRG), referred to in France as "en sus du GHS". During AAC the manufacturer either provides the medicine free of charge or invoices an "indemnity"—a temporary, company-set price for the product. For AAC, the maximum indemnity must be declared to the French Ministers after the first authorization. Agenus has declared a maximum indemnity for BOT/BAL in line with these rules. Ex-post rebate mechanisms apply where relevant.

"This is a breakthrough for patients and their physicians. MSS colorectal cancer resists currently approved immunotherapies, and available options to patients after standard regimens are scarce. On behalf of patients, families, and the clinical community, we thank ANSM, Assurance Maladie, and the Ministry for their leadership. We will support French centers without delay to ensure reliable supply of BOT/BAL and high quality real world

evidence,” commented Garo Armen, PhD, Chairman & CEO of Agenus.

Why it matters

Peer-reviewed and congress data show durable activity of BOT/BAL in refractory MSS mCRC, particularly in patients without active liver metastases—a population with limited options. Recent updates describe ~21-month median OS, ~42% 2-year survival, and ~20% ORR in expanded cohorts.

International patient access

European Union (EU) and the European Economic Area (EEA) patients may obtain planned care in France under Directive 2011/24/EU, usually with prior authorization for hospital or specialist care and reimbursement is provided by the patient’s home system based on its national tariffs. Outside the EU, countries such as Turkey operate treatment-abroad programs on a case-by-case basis. Patients should consult their National Contact Point or insurer as France’s reimbursement for French residents does not automatically extend to non-residents.

About France’s Compassionate Access (AAC)

AAC is a pre-authorization access route managed by ANSM for patients with serious or rare conditions without adequate alternatives. It is distinct from marketing authorization and from commercial pricing; coverage activates automatically at 100% for hospital use once authorized, with financing en sus du GHS and reimbursement at TTC purchase price.

About the BOT/BAL Phase 3 Program

Agenus will initiate the global Phase 3 BATTMAN trial ([NCT07152821](#)) in Q4 2025 to confirm efficacy in refractory MSS mCRC and support broader availability.

About Agenus

Agenus is a leading immuno-oncology company targeting cancer with a comprehensive pipeline of immunological agents. The company was founded in 1994 with a mission 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 has robust end-to-end development capabilities, across commercial and clinical cGMP manufacturing facilities, research and discovery, and a global clinical operations footprint. 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.

About Botensilimab (BOT)

Botensilimab (BOT) is a human Fc enhanced multifunctional anti-CTLA-4 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 1,200 patients have been treated with botensilimab and/or balstilimab 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.

About Balstilimab (BAL)

Balstilimab is a novel, fully human monoclonal immunoglobulin G4 (IgG4) designed to block PD-1 (programmed cell death protein 1) from interacting with its ligands PD-L1 and PD-L2. It has been evaluated in more than 900 patients to date and has demonstrated clinical activity and a favorable tolerability profile in several tumor types.

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 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 2024, 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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