



November 11, 2014

MacroGenics Provides Update on Corporate Progress and Third Quarter 2014 Financial Results

-- Four oncology molecules in clinical development; on track to have six by 2015 year-end

-- Margetuximab Phase 3 study in metastatic breast cancer to initiate in 2015

-- MGD007 (gpA33 x CD3 DART) first patients dosed in colorectal cancer

-- MGD011 (CD19 x CD3 DART) introduced

ROCKVILLE, Md., Nov. 11, 2014 (GLOBE NEWSWIRE) -- MacroGenics, Inc. (Nasdaq:MGNX), a clinical-stage biopharmaceutical company focused on discovering and developing innovative monoclonal antibody-based therapeutics for the treatment of cancer, as well as autoimmune disorders and infectious diseases, today provided a corporate progress update and reported financial results for the quarter ended September 30, 2014.

"With four oncology programs now in the clinic, including DARTs against both hematological malignancies and solid tumors, MacroGenics continues its expansion of breakthrough biologics. Key strategic decisions, including an improved margetuximab approach and an expanded relationship with Takeda, coupled with a strong financial position at the end of the third quarter, bolster our prominence in immuno-therapeutics," said Scott Koenig, M.D., Ph.D., President and CEO.

MacroGenics announced today that it will commence a pivotal Phase 3 study of margetuximab in HER2-positive metastatic breast cancer instead of MAGENTA, the previously planned Phase 3 clinical trial in third-line gastroesophageal cancer. Margetuximab, a monoclonal antibody enhanced using MacroGenics' proprietary Fc optimization technology, targets HER2, an antigen found in many breast, gastroesophageal and other solid tumor types. The new approach is based on clinical data for margetuximab in patients with breast cancer from ongoing Phase 1 expansion cohorts testing a once-every-three-week dosing regimen and the breadth of the opportunity to address the needs of breast cancer patients. Also, as a result of the rapidly changing landscape in the treatment of gastroesophageal cancer, new opportunities have been created to test margetuximab in innovative combination regimens that could be used in earlier lines of gastroesophageal cancer therapy. Accordingly, the Company also plans to initiate Phase 1/2 combination studies in patients with gastroesophageal cancer.

"This new direction for margetuximab is grounded in both emerging science and the data we have seen to date, as well as significant input from key opinion leaders and payers," commented Dr. Koenig. "In addition to advancing a potential new treatment for breast cancer patients, this approach will allow us to target a much larger population of patients. Further, this study is being designed to include an interim analysis to help de-risk the program, while maintaining our previous data read-out timeline," concluded Dr. Koenig.

MacroGenics also disclosed today that MGD011, a humanized CD19 x CD3 DART, will be one of the two new oncology-based DART candidates for which it intends to commence clinical development in 2015. MGD011 is designed to redirect T-cells to eliminate CD19-expressing cells found in many hematological malignancies and has been engineered to address half-life and manufacturing challenges posed by other programs targeting CD19 and CD3.

Update on Product Candidates

Margetuximab is an Fc-optimized monoclonal antibody that targets HER2. Recent highlights include:

- **New Phase 3 Breast Cancer Study:** The new Phase 3 pivotal study will evaluate margetuximab plus chemotherapy against the current standard of care in third-line metastatic breast cancer patients with HER2 expression at the 3+ level by immunohistochemistry (IHC) or 2+ level by IHC with gene amplification. The new Phase 3 study in breast cancer is anticipated to begin in the third quarter of 2015. MacroGenics projects that the time to regulatory filing for this indication should occur in a timeframe similar to that for the previously planned MAGENTA Phase 3 gastroesophageal cancer study.
- **Gastroesophageal Cancer Opportunity:** The Company plans to initiate Phase 1/2 combination studies in

gastroesophageal cancer and will no longer be pursuing the MAGENTA study.

- **Ongoing Phase 2a Clinical Study:** Patient enrollment continues in the Company's exploratory Phase 2a study in metastatic breast cancer patients with HER2 expression at the 1+ or 2+ level by IHC without gene amplification. The dosing of this study is being changed from once weekly to once every three weeks.

MGA271 is an Fc-optimized monoclonal antibody that targets B7-H3, a member of the B7 family of molecules involved in immune regulation. The Company recently initiated recruitment of patients in multiple additional monotherapy expansion cohorts across various tumor types, including triple-negative breast cancer, head and neck cancer, renal cell cancer, melanoma (after failing a previous immune therapy), and a cohort consisting of non-small cell lung cancer and bladder cancer patients with the highest level of B7-H3 expression. MacroGenics also plans to initiate further studies of MGA271 in combination with other therapies in 2015.

MGD006 is a Dual-Affinity Re-Targeting (DART) molecule that recognizes both CD123 and CD3. MacroGenics continues to enroll patients in a Phase 1 study of MGD006 for the treatment of acute myeloid leukemia.

MGD007 is a DART molecule that recognizes both the glycoprotein A33 antigen, or gpA33, and CD3. Recent highlights include:

- **Dosing Phase 1 Clinical Study:** MacroGenics recently began dosing patients in a Phase 1 study of MGD007 for the treatment of colorectal cancer. MGD007 represents the second DART molecule to enter the clinic, and the Company's first DART molecule dosed in patients with solid tumors.
- **Milestone Payment by Servier:** During the third quarter, MacroGenics received a \$5 million milestone payment from Servier triggered by the FDA clearance of the Phase 1 study. Servier has the option to obtain an exclusive license to develop and commercialize this program in all territories outside of North America, Japan, Korea, and India. MacroGenics retains development and commercialization rights to these territories.

MacroGenics' pipeline of earlier clinical candidates continues to progress. By year-end 2015, the Company expects to have two additional oncology-based DART molecules in the clinic as well as one autoimmune-based DART molecule. Updates on two of these disclosed programs include:

- **Continued Progress on MGD010:** MGD010 is a DART molecule that simultaneously targets CD32B and CD79B, which are two B-cell surface proteins. MGD010 is designed to inhibit B-cell activation by exploiting the inhibitory function of CD32B, a checkpoint molecule expressed by B cells. MGD010 is currently in pre-clinical development for the treatment of autoimmune disorders. MacroGenics expects to initiate a Phase 1a study in 2015. Upon completion of this study, Takeda will have the option to obtain an exclusive worldwide license for MGD010 by paying a license option fee, pursuant to a May 2014 collaboration agreement.
- **Introducing MGD011:** MGD011, a humanized CD19 x CD3 DART, is one of the two oncology-based DART candidates that MacroGenics intends to take into clinical development in 2015. The MGD011 pre-clinical data and the molecule's extended pharmacokinetic properties support dosing at intervals of once per week or longer.

Corporate Update

- **Expanded Takeda Relationship:** During the third quarter, MacroGenics and Takeda jointly announced that they entered into a collaboration agreement to develop and commercialize up to four product candidates, which are in addition to MGD010. Each of these product candidates will be directed against jointly selected pairs of molecular targets and incorporate MacroGenics' DART platform. Assuming successful development and commercialization by Takeda, MacroGenics could receive up to an additional approximately \$400 million in payments for each of the four potential product candidates.
- **Partnered Program Milestone:** During the third quarter, MacroGenics achieved a milestone for a DART program partnered with Boehringer Ingelheim that triggered a \$2 million payment due to MacroGenics.
- **Universal Shelf Registration Statement Filing:** MacroGenics intends to file a shelf registration statement with the SEC covering the potential sale of up to \$150 million of securities. Although MacroGenics expects to have the flexibility under the shelf registration statement, if and when it is declared effective, to more quickly access the capital markets with either equity or debt securities offerings, MacroGenics has no immediate plans to issue any such securities.

2014 Third Quarter Financial Results

- **Cash Position:** Cash and cash equivalents as of September 30, 2014 were \$179.2 million, compared to \$116.5 million as of December 31, 2013.
- **Revenue:** Total revenues, consisting primarily of revenue from collaborative research, were \$18.4 million for the quarter ended September 30, 2014, compared to \$20.2 million for the quarter ended September 30, 2013. Collaborative research revenue includes the recognition of deferred revenue from payments received in previous periods as well as payments received during the quarter.
- **R&D Expenses:** Research and development expenses were \$18.6 million for the quarter ended September 30, 2014,

compared to \$11.1 million for the quarter ended September 30, 2013.

- **G&A Expenses:** General and administrative expenses were \$3.7 million for the quarter ended September 30, 2014, compared to \$2.0 million for the quarter ended September 30, 2013.
- **Net Loss:** Net loss was \$3.9 million for the quarter ended September 30, 2014, compared to net income of \$6.6 million for the quarter ended September 30, 2013.
- **Shares Outstanding:** Shares outstanding as of October 31, 2014 were 27.8 million.

Conference Call Information

MacroGenics will host a conference call today at 4:15 pm (EST) to discuss the third quarter of 2014 and provide a corporate update. To participate in the conference call, please dial (877) 303-6253 (domestic) or (973) 409-9610 (international) five minutes prior to the start of the call and provide the Conference ID: 22748644.

The recorded, listen-only webcast of the conference call can be accessed under "Events & Presentations" in the Investor Relations section of the Company's website at <http://ir.macrogenics.com/events.cfm>. A replay of the webcast will be available shortly after the conclusion of the call and archived on the Company's website for 30 days following the call.

MACROGENICS, INC.
CONSOLIDATED BALANCE SHEET DATA
(Amounts in thousands)

	<u>September 30, 2014</u>	<u>December 31, 2013</u>
Cash and cash equivalents	\$ 179,191	\$ 116,481
Total assets	193,625	125,782
Deferred revenue	34,669	27,403
Total stockholders' equity	139,088	78,914

MACROGENICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(Amounts in thousands, except share and per share data)

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2014</u>	<u>2013</u>	<u>2014</u>	<u>2013</u>
Revenues:				
Revenue from collaborative research	\$ 18,283	\$ 20,111	\$ 41,886	\$ 42,016
Grant revenue	99	121	435	1,112
Total revenues	<u>18,382</u>	<u>20,232</u>	<u>42,321</u>	<u>43,128</u>
Costs and expenses:				
Research and development	18,632	11,088	50,536	32,234
General and administrative	3,678	1,986	11,081	7,323
Total costs and expenses	<u>22,310</u>	<u>13,074</u>	<u>61,617</u>	<u>39,557</u>
Income (loss) from operations	(3,928)	7,158	(19,296)	3,571
Other income (expense)	-	(554)	1	(627)
Net comprehensive income (loss)	<u>\$ (3,928)</u>	<u>\$ 6,604</u>	<u>\$ (19,295)</u>	<u>\$ 2,944</u>
Basic net income (loss) per common share	(\$0.14)	\$0.14	(\$0.71)	\$0.00
Diluted net income (loss) per common share	(\$0.14)	\$0.01	(\$0.71)	\$0.00
Basic weighted average common shares outstanding	27,751,437	1,184,507	27,227,151	1,463,798
Diluted weighted average common shares outstanding	27,751,437	21,242,979	27,227,151	21,908,859

About MacroGenics, Inc.

MacroGenics is a clinical-stage biopharmaceutical company focused on discovering and developing innovative monoclonal antibody-based therapeutics for the treatment of cancer, as well as autoimmune disorders and infectious diseases. The Company generates its pipeline of product candidates from its proprietary suite of next-generation antibody-based technology platforms. The combination of MacroGenics' technology platforms and protein engineering expertise has allowed the Company to generate promising product candidates and enter into several strategic collaborations with global pharmaceutical and biotechnology companies. For more information, please see the Company's website at www.macrogenics.com. MacroGenics and DART are registered trademarks of MacroGenics, Inc.

This press release shall not constitute an offer to sell or the solicitation of an offer to buy any securities, nor shall there be any sale of these securities in any state or jurisdiction in which the offer, solicitation or sale would be unlawful. This announcement is being issued pursuant to, and in accordance with, Rule 135 under the Securities Act of 1933, as amended.

Cautionary Note on Forward-Looking Statements

Any statements in this press release about future expectations, plans and prospects for the Company, including statements about the Company's strategy, future operations, clinical development of the Company's therapeutic candidates, milestone or opt-in payments from the Company's collaborators, the Company's future expectations and plans and prospects and other statements containing the words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the uncertainties inherent in the initiation and enrollment of future clinical trials, expectations of expanding ongoing clinical trials, availability and timing of data from ongoing clinical trials, expectations for regulatory approvals, other matters that could affect the availability or commercial potential of the Company's product candidates and other risk factors described in the Company's filings with the Securities and Exchange Commission, including those discussed in the "Risk Factors" section of the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 20, 2014 and the subsequent Quarterly Reports on Form 10-Q. In addition, the forward-looking statements included in this press release represent the Company's views as of the date hereof. The Company anticipates that subsequent events and developments will cause the Company's views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date hereof.

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