

MacroGenics Provides Update on Corporate Progress and Second Quarter 2015 Financial Results

- -- Fourth bi-specific DART® molecule, MGD011, in clinical testing
- -- Margetuximab Phase 3 SOPHIA metastatic breast cancer study initiated
- -- Balance sheet strengthened with completion of \$141 million equity offering

ROCKVILLE, Md., Aug. 05, 2015 (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 second quarter ended June 30, 2015.

"In focusing on our mission to harness the power of the immune system to fight cancer and autoimmune diseases, we continue to make advancements across multiple fronts," said Scott Koenig, M.D., Ph.D., President and CEO of MacroGenics. "Our fourth bi-specific DART molecule, MGD011, is in clinical testing with our collaboration partner, Janssen Biotech, Inc., and we expect that our fifth DART molecule, MGD009, will be in the clinic by year-end. In addition, we recently initiated SOPHIA, our Phase 3 study of margetuximab in patients with metastatic breast cancer. Beyond these programs, we continue to advance our other DART molecules as well as MGA271, an Fc-optimized antibody product candidate. Finally, with the additional capital recently raised, we are in an excellent position to accelerate the development of checkpoint inhibitor molecules as well as to expand our manufacturing capacity for anticipated clinical and commercial needs."

Pipeline Update

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

- SOPHIA Phase 3 Metastatic Breast Cancer Study: The Company recently enrolled the first patient in SOPHIA, a Phase 3 pivotal study. This randomized, open-label, two-arm, interventional Phase 3 study will evaluate margetuximab plus chemotherapy against trastuzumab plus chemotherapy in third-line metastatic breast cancer patients with HER2 expression at the 3+ level by IHC or 2+ level by IHC with gene amplification. The purpose of the study is to determine whether patients treated with margetuximab plus chemotherapy have longer progression-free and overall survival than patients treated with trastuzumab plus chemotherapy. MacroGenics plans to enroll 530 patients in this study and projects that it will take approximately three years to complete.
- ASCO Presentation of Phase 1 Data: During the second quarter, MacroGenics presented margetuximab Phase 1 clinical data at the 2015 American Society of Clinical Oncology (ASCO) Annual Meeting in a poster discussion. Margetuximab was well tolerated by patients in this dose-escalation study and showed promising activity in patients who have limited treatment options. The updated Phase 1 study results show the potential for margetuximab in the treatment of HER2-expressing tumors.
- **Gastroesophageal Cancer Opportunity**: The Company remains on track to initiate a Phase 1/2 combination study in gastroesophageal cancer starting in the fourth quarter of 2015.

MGA271 is an Fc-optimized monoclonal antibody that targets B7-H3, a member of the B7 family of molecules involved in immune regulation. Recent highlights include:

Recruiting Additional Monotherapy Expansion Cohorts: The Company is recruiting patients in multiple MGA271
monotherapy expansion cohorts in a Phase 1 study across various tumor types, including triple-negative breast cancer,
head and neck cancer, renal cell cancer, melanoma (in patients who have progressed despite prior checkpoint inhibitor
treatment), non-small cell lung cancer and bladder cancer.

- Combination Studies: MacroGenics is currently enrolling a study of MGA271 in combination with ipilimumab in patients with B7-H3 positive melanoma, lung, and head and neck cancers. In the third quarter of 2015, the Company also expects to initiate a study of MGA271 in combination with pembrolizumab in patients with melanoma, non-small cell lung carcinoma and squamous cell carcinoma of the head and neck.
- Presentation of Phase 1 MGA271 Data: In the fourth quarter of 2015, MacroGenics plans to present clinical data from the ongoing clinical trial.

MGD006 is a humanized DART molecule that recognizes both CD123 and CD3. CD123, the Interleukin-3 receptor alpha chain, is expressed on leukemia and leukemic stem cells. The primary mechanism of action of MGD006 is its ability to redirect T cells, via their CD3 component, to kill CD123-expressing cells. MacroGenics continues to enroll patients in the dose escalation portion of a Phase 1 study of MGD006 for the treatment of acute myeloid leukemia.

MGD007 is a humanized DART molecule that recognizes both the glycoprotein A33 antigen, or gpA33, and CD3. gpA33 is a gastrointestinal antigen with high expression in colorectal cancer. The primary mechanism of action of MGD007 is its ability to redirect T cells, via their CD3 component, to kill gpA33-expressing cells. MacroGenics continues to enroll patients in the dose escalation portion of a Phase 1 study of MGD007 for the treatment of colorectal cancer.

MGD010 is a humanized DART molecule that simultaneously targets CD32B and CD79B, two B-cell surface proteins. MGD010 is being developed for the treatment of autoimmune disorders and is designed to inhibit B-cell activation by exploiting the inhibitory function of CD32B, a checkpoint molecule expressed by B cells. MacroGenics continues to enroll patients in a Phase 1a study in normal healthy volunteers.

MGD011 is a humanized DART molecule that targets both CD19 and CD3 and is being developed for the treatment of B-cell hematological malignancies. MGD011 is designed to redirect T cells, via their CD3 component, to eliminate cells expressing CD19, a marker expressed in B-cell hematological malignancies. MGD011 has been engineered to address half-life challenges posed by other programs targeting CD19 and CD3, allowing for convenient intermittent dosing regimens in the clinical setting.

Pursuant to a collaboration agreement executed with Janssen Biotech, Inc. in December 2014, Janssen is developing MGD011. The first patient in an open-label Phase 1 study received the first dose of MGD011 in late July, triggering a \$10 million milestone payment to MacroGenics. Janssen's Phase 1 study will evaluate the safety, tolerability and preliminary clinical activity of MGD011 when administered to patients with relapsed or refractory B-cell malignancies, including diffuse-large B cell lymphoma, follicular lymphoma, mantle-cell lymphoma, chronic lymphocytic leukemia and acute lymphoblastic leukemia. MacroGenics retains options to co-promote the product in the United States and Canada and to invest in later-stage development in exchange for a profit-share.

MacroGenics continues to advance several additional antibody and DART-based pre-clinical molecules, including MGD009, for which MacroGenics retains worldwide development and commercialization rights.

Corporate Update

- Equity Offering: In July, the Company completed an equity offering, raising \$141 million in net proceeds, which includes exercise of the underwriters' option to acquire additional shares in full. MacroGenics intends to use the proceeds of this offering to expand its manufacturing capacity, accelerate development of undisclosed immune checkpoint-based product candidates, advance other research and development programs, in-license or acquire other products or technologies, or for general corporate purposes.
- Manufacturing Expansion: The Company recently signed a lease for additional space with a focus on expanding its commercial manufacturing capabilities. MacroGenics expects to complete the design of the new manufacturing space this year.
- R&D Day: The Company plans to host an R&D Day in New York on Tuesday, October 13, 2015.

Second Quarter 2015 Financial Results

- Cash Position: Cash and cash equivalents as of June 30, 2015 were \$235.0 million, compared to \$157.6 million as of December 31, 2014. Subsequent to June 30, 2015, MacroGenics completed an equity offering of 4,053,750 shares (including full exercise of the underwriters' option to acquire additional shares) with net proceeds of \$141 million to the Company.
- Revenue: Total revenues, consisting primarily of revenue from collaborative research, were \$6.7 million for the three-month period ended June 30, 2015 compared to \$9.2 million for the three-month period ended June 30, 2014.
 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 \$22.7 million for the three-month period ended June 30, 2015, compared to \$17.3 million for the three-month period ended June 30, 2014. This increase was primarily due to recently commenced clinical trial activities and preparations for additional studies, offset in part by a decrease in

- expenses related to a product candidate transferred to a partner following IND submission.
- **G&A Expenses**: General and administrative expenses were \$5.3 million for the three-month period ended June 30, 2015, compared to \$4.1 million for the three-month period ended June 30, 2014. This increase was primarily due to higher stock-based compensation expense and labor costs as well as information technology-related expenses.
- **Net Loss**: Net loss was \$21.4 million for the three-month period ended June 30, 2015, compared to net loss of \$12.3 million for the three-month period ended June 30, 2014.
- **Shares Outstanding**: Shares outstanding as of June 30, 2015 were 30,123,407, excluding the 4,053,750 shares issued in connection with the July equity offering.

Conference Call Information

MacroGenics will host a conference call today at 4:30 pm (EDT) to discuss the second quarter 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: 94573989.

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)

	June 3	30, 2015	Decem	ber 31, 2014
Cash and cash equivalents	\$ 2	35,027	\$	157,591
Total assets	2	54,203		173,886
Deferred revenue		22,908		30,720
Total stockholders' equity	2	11,689		121,286

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

	Tł	ree Months En	ded June 30, S	Six Months Ended June 30,		
		2015	2014	2015	2014	
Revenues:						
Revenue from collaborative research	\$	5,598 \$	9,202 \$	76,763 \$	23,603	
Grant revenue		1,118	18	1,232	336	
Total revenues		6,716	9,220	77,995	23,939	
Costs and expenses:						
Research and development		22,660	17,335	44,124	31,904	
General and administrative		5,346	4,145	10,029	7,403	
Total costs and expenses		28,006	21,480	54,153	39,307	
Income (loss) from operations		(21,290)	(12,260)	23,842	(15,368)	
Other income (expense)		(86)	1	(89)	1	
Net comprehensive income (loss)	\$	(21,376)\$	(12,259)\$	23,753 \$	(15,367)	
Basic net income (loss) per common share	\$	(0.71)\$	(0.44) \$	0.80 \$	(0.57)	
Diluted net income (loss) per common share	\$	(0.71)\$	(0.44) \$	0.75 \$	(0.57)	
Basic weighted average number of common shares		30,059,329	27,651,297	29,739,326	26,960,664	
Diluted weighted average number of common shares	3	30,059,329	27,651,297	31,797,332	26,960,664	

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.

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 anticipated milestones and future expectations and plans and prospects for the Company 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. 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 forwardlooking statements at some point in the future, the Company specifically disclaims any obligation to do so. These forwardlooking statements should not be relied upon as representing the Company's views as of any date subsequent to the date hereof.

Contacts:

Jim Karrels, Senior Vice President, CFO

MacroGenics, Inc.

1-301-251-5172, info@macrogenics.com

Karen Sharma, Vice President

MacDougall Biomedical Communications

1-781-235-3060, ksharma@macbiocom.com

Source: MacroGenics, Inc.

News Provided by Acquire Media