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SAFC® Invests in Commercial-Scale ADC Conjugation Manufacturing and Services; Expands HPAPI Manufacturing and Storage Capacity

Investments broaden SafeBridge™ certified manufacturing capacity to support customer demand and ensure supply chain continuity for SAFC Contract Manufacturing Services and Solutions customers

ST. LOUIS, Oct. 14, 2013 /PRNewswire/ -- Sigma-Aldrich Corporation's (NASDAQ: SIAL) custom manufacturing services business unit, SAFC® Commercial (www.sigma-aldrich.com/safc), is expanding two of its manufacturing facilities in the United States to support drug manufacturers in efficiently bringing new targeted and cytotoxic therapies to market. As a direct result of increasing customer demand, SAFC is investing in commercial-scale manufacturing capacity for antibody drug conjugates (ADCs) in St. Louis, MO, and expanding its high-potency active pharmaceutical ingredient (HPAPI) manufacturing and storage at the Verona facility near Madison, WI.

“These strategic investments are the result of ongoing dialogue with customers. We are directly addressing their needs for supply chain continuity when sourcing the high-quality manufacturing materials, technologies and services that drive the performance of their end products,” said Gilles Cottier, President of SAFC. “Bringing commercial-scale ADC capacity to St. Louis and augmenting the offer at Verona to feature expanded HPAPI manufacturing and storage capabilities are direct reflections of SAFC’s commitment to investing in support of our customers.”

The ADC expansion at the St. Louis site is expected to be completed by mid-2015. The updated facility will feature segregated areas for high-potent solids handling, manufacturing and aseptic bulk filling of product. Batches up to 600L/3kg can be manufactured under ISO 7 classification and the facility is suitable for HPAPI containment for SafeBridge™ Category 4 compounds. Additional commercial-scale manufacturing capacity has also been designed to seamlessly accommodate future growth in demand for ADC production.

“Once complete, the St. Louis expansion will enable continuous scale-up of ADCs from preclinical to clinical phases and into commercial-scale production,” said Head of Global Strategic Marketing for Contract Manufacturing Services & Solutions at SAFC Andreas Weiler. “ADC technologies have shown exceptional promise in targeted therapies for chronic diseases, such as cancer, so strategic investments in this facility made sense to support our customers through all phases of ADC innovation.”

“The investments at the St. Louis and Verona sites are complementary and allow SAFC to offer continuity for customers’ drug development and commercialization programs,” said Dave Bormett, Director of Operations for SAFC. “Verona’s HPAPI handling and containment standards ( < 0.1 microgram/M³) enable the site to manufacture the high-potency toxins and linkers that the St. Louis site uses to conjugate biological molecules and develop ADCs. It is all a part of our drive to provide customers with complete solutions based on our expertise in niche technologies.”

Online since mid-2010, and SafeBridge certified in October 2011, Verona was originally constructed as an add-on to the Madison facility for cGMP manufacture of late-phase and commercial HPAPIs requiring 200 to 4,000 liters capacity. By mid-2014, the site will have a new warehouse with storage capacity for raw materials, as well as three new cGMP manufacturing areas to support projects. Two of the areas will be designated for smaller lab-scale manufacturing in the kilo range, while the other will accommodate larger-scale manufacturing up to 800 liters. The facility expansion will also provide space for growth of SAFC’s product stability sample storage and testing service, as well as a process scale-up lab to support GMP production.

SAFC will be at the World ADC Summit in San Francisco from October 14 to 16 and at CPhI Worldwide in Frankfurt, Germany, from October 22 to 24 in Hall 5.1 at booth B36.

The foregoing release contains forward-looking statements that can be identified by terminology such as "expected," "will feature," "future growth," "will enable," "will have," "will be," "will accommodate" "will provide" or similar expressions, or by expressed or implied discussions regarding potential future revenues from products derived there from. You should not place undue reliance on these statements. There can be no guarantee that the products in SAFC’s service offering will continue to meet the demands of the marketplace. Nor can there be any guarantee that any of these products and services will achieve any particular levels of revenue in the future. Such forward-looking statements reflect the current views of management regarding future events, and involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. In particular, management’s expectations regarding these products could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally; the Company’s ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; government, industry and general public pricing pressures;
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**About SAFC:** SAFC Commercial, the custom manufacturing and services business unit of Sigma-Aldrich Corporation, is recognized as a top 10 global specialty chemicals and biologics supplier. As a trusted manufacturer for the life science and high technology industries, SAFC works closely with customers to resolve development challenges and accelerate the product pipeline utilizing its global "Centers of Excellence" and dedicated manufacturing facilities. Its rich portfolio includes high-purity inorganic materials for high technology applications, critical raw materials and extensive biologics safety testing services for biopharmaceutical manufacturing, and complex, high-potent APIs and key intermediates for pharmaceutical manufacturing. For more information, visit [SAFC Commercial](#).

**About Sigma-Aldrich:** Sigma-Aldrich is a leading Life Science and High Technology company whose biochemical, organic chemical products, kits and services are used in scientific research, including genomic and proteomic research, biotechnology, pharmaceutical development, the diagnosis of disease and as key components in pharmaceutical, diagnostics and high technology SAFC manufacturing. Sigma-Aldrich customers include more than 1.3 million scientists and technologists in life science companies, university and government institutions, hospitals and industry. The Company operates in 38 countries and has nearly 9,100 employees whose objective is to provide excellent service worldwide. Sigma-Aldrich is committed to accelerating customer success through innovation and leadership in Life Science and High Technology. For more information about Sigma-Aldrich, please visit its website at [www.sigma-aldrich.com](http://www.sigma-aldrich.com).

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