



Current Agreements

Dealdoc

Development, manufacturing and marketing agreement for NEPHROCHECK Test

Ortho-Clinical Diagnostics
Astute Medical

Jul 28 2014

Development, manufacturing and marketing agreement for NEPHROCHECK Test

Companies:	Ortho-Clinical Diagnostics Astute Medical
Announcement date:	Jul 28 2014
Deal value, US\$m:	n/d
Related contracts:	Distribution agreement for Nephrocheck test and Astute140

- [Details](#)
- [Financials](#)
- [Term sheet](#)
- [Press Release](#)
- [Filing Data](#)
- [Contract](#)

Details

Announcement date:	Jul 28 2014
Industry sectors:	Biotech Diagnostic Research tools
Brand name:	NEPHROCHECK, ASTUTE140
Exclusivity:	Semi-exclusive
Therapy areas:	Genitourinary » Acute kidney injury
Technology types:	Biomarkers Diagnostics Development Licensing
Deal components:	Manufacturing Marketing
Geographic focus:	Europe

Financials

Deal value, US\$m:	n/d
---------------------------	-----

Term sheet

March 2017

Ortho Clinical Diagnostics, a global leader of in vitro diagnostics, announced that it has expanded its agreement with Astute Medical, Inc. for distribution of the NephroCheck Test, a biomarker-based test that aids in risk assessment for acute kidney injury.

Under the new agreement, Astute Medical has granted Ortho distribution rights in additional European countries, enhancing customer access to a test that is changing the way hospital physicians approach acute kidney injury (AKI), a common and dangerous complication.

July 2014

OCD also receives a semi-exclusive license to develop, manufacture and sell the NEPHROCHECK Test for use on its VITROS line of automated, high-volume testing platforms.

The NEPHROCHECK® Test and ASTUTE140® Meter are used in a hospital setting to assess critically-ill patients for risk of acute kidney injury (AKI), an increasing burden worldwide that can lead to poor patient outcomes and increased healthcare expenditures if not detected at an early stage.

Astute will be responsible for manufacturing the Astute NEPHROCHECK Test for use on the ASTUTE140 Meter in all markets and will collaborate with OCD on the sale of the NEPHROCHECK Test.

Press Release

March 2017

RARITAN, N.J., March 13, 2017 /PRNewswire/ -- Ortho Clinical Diagnostics ("Ortho"), a global leader of in vitro diagnostics, today announced that it has expanded its agreement with Astute Medical, Inc. for distribution of the NephroCheck Test, a biomarker-based test that aids in risk assessment for acute kidney injury. Under the new agreement, Astute Medical has granted Ortho distribution rights in additional European countries, enhancing customer access to a test that is changing the way hospital physicians approach acute kidney injury (AKI), a common and dangerous complication.

"Ortho is committed to helping our lab customers identify patients with risk for moderate to severe AKI, which has been shown to help physicians to better manage their critically ill patients and improve outcomes," said Alex Socarrás, Ortho's executive vice president, commercial operations. "We look forward to bringing the important NephroCheck Test to a broader market in Europe."

Today, up to 50 percent of severely ill patients develop AKI, which can result in prolonged hospital stays, long-term complications, greater risk of mortality, and higher cost of care. An outcomes study published recently by the journal Intensive Care Medicine reported a 33.9 percent reduction in the occurrence of moderate to severe AKI following cardiac surgery when clinicians used the NephroCheck Test to identify patients with moderate to severe risk for AKI and then implemented a bundle of care recommended by the Kidney Disease Improving Global Outcomes (KDIGO) guidelines.

"As the body of evidence demonstrating the value of assessing kidney stress before damage occurs continues to grow, we become ever more committed to distributing the NephroCheck Test to a broad audience," said Ryan Roberts, Astute Medical's chief commercial officer. "Our expanded agreement with Ortho will help even more hospitals shift the AKI paradigm from diagnosis to prevention."

The new agreement builds upon Astute Medical's licensing and collaboration agreements with Ortho. In 2014, Astute Medical granted Ortho a license to develop and market the NephroCheck Test for Ortho's VITROS® line of automated, high-volume testing platforms in the United States and certain countries in Europe. Ortho also commercializes Astute Medical's NephroCheck Test on the Astute140 platform in the United States.

Important Information About The NephroCheck Test In the United States, the NephroCheck Test System is intended to be used in conjunction with clinical evaluation in patients who currently have or have had within the past 24 hours acute cardiovascular and or respiratory compromise and are intensive care unit (ICU) patients as an aid in the risk assessment for moderate or severe AKI within 12 hours of patient assessment. The NephroCheck Test System is intended to be used in patients 21 years of age or older.

For more information visit NephroCheck.com.

In the EU, the NephroCheck Test result is intended to be used in conjunction with clinical evaluation as an aid in the risk assessment of acute kidney injury in the critically ill. The NephroCheck Test is CE-marked and available in Europe.

Astute Medical's NephroCheck Test received 510(k)-clearance through the FDA's de novo classification. The test is indicated for prescription use only.

About Ortho Clinical Diagnostics Ortho Clinical Diagnostics is a global leader of in vitro diagnostics serving the clinical laboratory and immunohematology communities. Across hospitals, hospital networks, blood banks and labs in more than 120 countries, Ortho's high-quality products and services enable health care professionals to make better-informed treatment decisions. For the immunohematology community, Ortho's blood typing products help ensure every patient receives blood that is safe, the right type and the right unit. Ortho brings sophisticated testing technologies, automation, information management and interpretation tools to clinical laboratories around the world to help them run more efficiently and effectively and improve patient care. Ortho's purpose is to improve and save lives with diagnostics, and it does that by reimagining what's possible. This is what has defined Ortho for more than 75 years, and it's what drives Ortho forward. For more information, visit www.orthoclinicaldiagnostics.com.

About Astute Medical, Inc. Astute Medical is dedicated to improving the diagnosis of high-risk medical conditions and diseases through the identification and validation of protein biomarkers that can serve as the basis for novel diagnostic tests.

The Company's focus is community- and hospital-acquired acute conditions that require rapid diagnosis and risk assessment. Astute Medical's current areas of interest include abdominal pain, acute coronary syndromes, cerebrovascular injury, kidney injury and sepsis.

July 2014

Ortho-Clinical Diagnostics Signs Agreement With Astute Medical To Commercialize And Develop Innovative Acute Kidney Injury Tests

Ortho-Clinical Diagnostics, Inc. (OCD) announced it has entered into a strategic partnership with Astute Medical, Inc., under which OCD will become the exclusive commercial partner for the distribution of Astute's NEPHROCHECK® Test and ASTUTE140® Meter in certain markets in Europe and, pending FDA clearance, the United States. On June 30, 2014, OCD became an independent, stand-alone diagnostics company with a renewed commitment to expand market reach with differentiated platforms and menus to better serve lab customers.

The NEPHROCHECK® Test and ASTUTE140® Meter are used in a hospital setting to assess critically-ill patients for risk of acute kidney injury (AKI), an increasing burden worldwide that can lead to poor patient outcomes and increased healthcare expenditures if not detected at an early stage.

"Our collaboration with Astute Medical is aligned with OCD's focus on providing access to the differentiated innovation that enables our customers to better address and manage critical healthcare needs," said OCD Chairman and Chief Executive Officer Dr. Martin D. Madaus. "This commercial and development alliance will expand OCD's ability to meet the needs of our customers and we are pleased to announce this agreement with Astute early into our existence as a stand-alone company."

"We are delighted to partner with OCD and see great potential to expand access to Astute Medical's innovative kidney injury assessment tools through their commercial reach and unique development capabilities," said Chris Hibberd, Astute Medical Chief Executive Officer.

Under the agreement, OCD also receives a semi-exclusive license to develop, manufacture and sell the NEPHROCHECK® Test for use on its VITROS® line of automated, high-volume testing platforms. In addition, as part of this strategic agreement, OCD has made a \$15 million equity investment in Astute Medical. Astute will be responsible for manufacturing the Astute NEPHROCHECK® Test for use on the ASTUTE140® Meter in all markets and will collaborate with OCD on the sale of the NEPHROCHECK® Test.

About Ortho-Clinical Diagnostics, Inc.

Ortho-Clinical Diagnostics, Inc. delivers high-quality in vitro diagnostic products that give healthcare professionals around the world the knowledge they need to make better treatment decisions sooner. The company serves the global transfusion medicine community with donor screening and blood typing products to help ensure every patient receives blood that is safe, the right type and the right unit. Ortho-Clinical Diagnostics also brings sophisticated information management, testing technologies and automation and interpretation tools to clinical laboratories worldwide to help them run more efficiently and improve patient care. For more information, visit www.orthoclinical.com.

About Astute Medical, Inc.

Named by the Wall Street Journal as one of the Top 10 Healthcare Start-Ups of 2012, Astute Medical is dedicated to improving the diagnosis of high-risk medical conditions and diseases through the identification and validation of protein biomarkers that can serve as the basis for novel diagnostic tests. The Company's focus is community and hospital-acquired acute conditions that require rapid diagnosis and risk assessment. Astute Medical's current areas of interest include abdominal pain, acute coronary syndromes, cerebrovascular injury, kidney injury and sepsis.

Filing Data

Not available.

Contract

Not available.