



Mallinckrodt Pharmaceuticals

OFIRMEV® (Acetaminophen) Injection Health Economic Data Presented at 41st Annual Regional Anesthesiology and Acute Pain Medicine Meeting

March 31, 2016

-- Retrospective data show treating acute surgical pain with OFIRMEV and reduced opioid use: decreased hospital length of stay, resulted in fewer potential opioid-related complications and lowered costs --

CHESTERFIELD, United Kingdom, March 31, 2016 /PRNewswire/ -- [Mallinckrodt plc](#) (NYSE: MNK), a leading global specialty biopharmaceutical company, today announced the results from a retrospective analysis of health economic data on the use of OFIRMEV (acetaminophen) injection and reduced opioid use for the treatment of acute surgical pain. The results were presented as a moderated ePoster at the 41st Annual Regional Anesthesiology and Acute Pain Medicine Meeting on Thursday, March 31, in New Orleans.

The analysis, titled "**Estimating the Effect of Intravenous Acetaminophen (IV-APAP) on Length of Stay and Inpatient Costs**," evaluated data from The Advisory Board Company's database of more than 2.2 million anonymous adult inpatient surgical admissions across 297 U.S. hospitals from 2012 to 2014. This non-comparative, retrospective analysis modeled length of stay¹ as well as potential opioid-related complications and related costs, based on an annual impact for a "medium-sized" hospital², among surgical patients where there was both a one-level reduction in opioid use (high to medium, medium to low, or low to none) and the use of IV acetaminophen therapy to help manage acute surgical pain. This included patients undergoing cardiovascular, colorectal, general, obstetrics/gynecology, orthopedics and spine surgeries.

Key findings associated with incorporating OFIRMEV and reducing the use of opioids across these surgical patients were:

- An average 18% reduction in length of stay for the modeled scenario with an estimated annual cost savings of \$4.5 million;
- An average reduction in modeled complication rates of 28.5% with an estimated annual cost-savings of \$200,000; and
- In aggregate, an estimated annual \$4.7 million in lowered costs, per a medium-sized hospital.

ABOUT THE DATA

Estimating the effect of intravenous acetaminophen (IV-APAP) on length of stay and inpatient costs. Eve Shaffer, MS, The Advisory Board Company, Washington, DC.

Find the poster online: http://epostersonline.com/asra_RA16/node/723

IMPLICATIONS OF THE DATA

This analysis may provide important insight for surgeons, pharmacists and hospital administrators looking for possible ways to help improve patient outcomes and provide savings to the hospital system. The use of opioids alone has been a mainstay for acute pain management. There is an overreliance on opioids as monotherapy to treat acute pain in U.S. hospitals today and 7 out of 10 hospital patients treated with intravenous (IV) analgesia receive IV opioids alone.³

LIMITATIONS OF STUDY

Limitations associated with retrospective observational research designs include the following: ability to make causal inferences, reproducibility and generalizability.

ABOUT OFIRMEV (Acetaminophen) Injection

OFIRMEV (acetaminophen) injection is indicated for the management of mild to moderate pain, management of moderate to severe pain with adjunctive opioid analgesics, and reduction of fever. OFIRMEV (acetaminophen) injection is the first and only intravenous (IV) formulation of acetaminophen to be approved in the United States. The U.S. Food and Drug Administration approved OFIRMEV in November 2010. OFIRMEV is available to hospitals and outpatient and ambulatory surgical centers across the U.S.

IMPORTANT RISK INFORMATION

WARNING: RISK OF MEDICATION ERRORS AND HEPATOTOXICITY

Take care when prescribing, preparing, and administering OFIRMEV Injection to avoid dosing errors which could result in accidental overdose and death. In particular, be careful to ensure that:

- the dose in milligrams (mg) and milliliters (mL) is not confused;
- the dosing is based on weight for patients under 50 kg;
- infusion pumps are properly programmed; and

- the total daily dose of acetaminophen from all sources does not exceed maximum daily limits.

OFIRMEV contains acetaminophen. Acetaminophen has been associated with cases of acute liver failure, at times resulting in liver transplant and death. Most of the cases of liver injury are associated with the use of acetaminophen at doses that exceed the recommended maximum daily limits, and often involve more than one acetaminophen-containing product.

CONTRAINDICATIONS

- Acetaminophen is contraindicated in patients with:
 - known hypersensitivity to acetaminophen or to any of the excipients in the intravenous (IV) formulation.
 - severe hepatic impairment or severe active liver disease

ADVERSE REACTIONS

- Serious adverse reactions may include hepatic injury, serious skin reactions, hypersensitivity, and anaphylaxis.
- Common adverse reactions in adults include nausea, vomiting, headache, and insomnia. Common adverse reactions in pediatric patients include nausea, vomiting, constipation, pruritus, agitation, and atelectasis.

For additional Important Risk Information, including complete boxed warning, see [Full Prescribing Information](#).

ABOUT MALLINCKRODT

Mallinckrodt is a global business that develops, manufactures, markets and distributes specialty pharmaceutical and biopharmaceutical products and therapies, as well as nuclear imaging products. Areas of focus include autoimmune and rare diseases in specialty areas like neurology, rheumatology, nephrology and pulmonology; immunotherapy and neonatal respiratory critical care therapies; analgesics and hemostasis products; and central nervous system drugs. The company's core strengths include the acquisition and management of highly regulated raw materials and specialized chemistry, formulation and manufacturing capabilities. The company's Specialty Brands segment includes branded medicines; its Specialty Generics segment includes specialty generic drugs, active pharmaceutical ingredients and external manufacturing; and the Nuclear Imaging segment includes nuclear imaging agents. To learn more about Mallinckrodt, visit www.mallinckrodt.com.

Mallinckrodt uses its website as a channel of distribution of important company information, such as press releases, investor presentations and other financial information. It also uses its website to expedite public access to time-critical information regarding the company in advance of or in lieu of distributing a press release or a filing with the U.S. Securities and Exchange Commission (SEC) disclosing the same information. Therefore, investors should look to the Investor Relations page of the website for important and time-critical information. Visitors to the website can also register to receive automatic e-mail and other notifications alerting them when new information is made available on the Investor Relations page of the website.

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¹ The average number of days a patient stays at the facility

² American Hospital Association definition of 'medium sized' hospital is 100-399 beds

³ Premier Healthcare Alliance [paid-access hospital research database: data from January 2011-March 2015]. Charlotte, NC : Premier, Inc. Updated June 2015 .

Logo - <http://photos.prnewswire.com/prnh/20150105/167103LOGO>

To view the original version on PR Newswire, visit: <http://www.prnewswire.com/news-releases/ofirmev-acetaminophen-injection-health-economic-data-presented-at-41st-annual-regional-anesthesiology-and-acute-pain-medicine-meeting-300244230.html>