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The FIRM trial a large double-blind randomized controlled trial of ferumoxytol vs. ferric carboxymaltose for the treatment of Iron Deficiency Anemia

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Over the past 2 decades IV iron preparations have found widespread usage in multiple disease states resulting in IDA which has been inadequately treated with oral irons. Yet, there is a remarkable paucity of large controlled studies comparing these agents head to head , especially of sufficient size to assess the incidence of rare adverse events such as hypersensitivity reactions and major hypotension. The 2 most recently approved IV iron agents in the US, ferumoxtytol (Fer) and ferric carboxymaltose (FCM) are able to deliver a full course of iron administered in 2 doses. The FIRM study (IDA-304) is a multicenter study conducted in ~180 sites in North America and Europe. Just over 2,000 patients with a diagnosis of IDA of any etiology, who are intolerant to oral iron, received either 2x510mg of Fer, or 2x750mg of FCM in a double blind fashion. Efficacy is assessed by mean change in hemoglobin and change in hemoglobin/mg of iron over the 5 week study. Safety focuses on the occurrence of moderate or severe hypersensitivity reactions (HSRs), including anaphylaxis, and moderate to severe hypotension. All potential HSRs are adjudicated by a blinded Clinical Events Committee. 2015 patients have been randomized, with the final patient visit in January 2017. Results will be available during 2Q17 and presented.

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