1054. Immunogenicity And Safety of Quadrivalent Influenza Vaccine Administered Intradermally (ID) in Adults 18 through 64 Years of Age

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Background. The investigational ID Quadrivalent Inactivated Influenza vaccine (IIV4-ID) was developed from licensed split-virion trivalent influenza vaccine (IIV3-ID1, Fluzone® Intradermal) by adding a second B strain hemagglutinin (HA) antigen of the alternate B lineage (Victoria). A Phase III study was conducted during the 2012-13 influenza season to show that the addition of a second B strain does not interfere with the immune response to the other vaccine HA components or alter the safety profile.

Methods. The vaccines were administered ID at 9 µg HA per virus strain to adults 18-64 years old using the BD Soluvia™ microinjection system. IIV3-ID1 contained the 2012-13 year B Yamagata lineage strain and IIV3-ID2 contained the alternate B Victoria lineage. Hemagglutination inhibition (HAI) antibody titers were measured in 2/3 of pre- and 28 day post vaccination paired sera. Injection-site and systemic reactions, and adverse events (AEs) were recorded.

Results. 1,676 subjects received IIV4-ID, 837 the licensed IIV3-ID1 and 847 the investigational IIV3-ID2. IIV4-ID induced robust immune responses in terms of geometric mean HAI titers (GMTs), seroconversion rates (SCRs; 4-fold rise in HAI titer pre- to post vaccination) and seroprotection rates (HAI titer $\geq$ 1:40) for all 4 virus strains. The immune response to IIV4-ID was statistically non-inferior for the 4 virus strains assessed by GMT ratios (GMTRs) and SCRs vs the control IIV3-ID vaccines. GMTRs and SCRs to both B strains in IIV4-ID were statistically superior to the IIV3-ID without the corresponding B strain. IIV4-ID had a safety profile similar to the two IIV-3ID groups. The most commonly reported solicited reactions were pain, pruritus, myalgia, headache, and malaise, and most were mild or moderate, occurring within 3 days of vaccination. IIV4-ID was statistically non-inferior to the two IIV3-ID vaccines in terms of rates of at least one grade 2 or 3 systemic reaction.

Conclusion. IIV4-ID was well-tolerated without safety concerns. Antibody responses to B strains in the IIV4-ID were superior to IIV3-ID containing the alternate strain and non-inferior for the A and matched B strains. By avoiding vaccine B strain mismatch to the circulating strain, IIV4-ID could improve vaccine efficacy.

Disclosures. **G. J. Gorse**, Sanofi Pasteur: Investigator and Spouse is shareholder, Reimbursable travel expenses **A. Falsey**, Regeneron: Consultant, Consulting fee; Hologic: Consultant, Consulting fee; Sanofi Pasteur: Research Contractor, Research grant; AstraZeneca: Research Contractor, Research grant; ADMA Biologic Inc.: Research Contractor, Research grant **V. Landolfi**, Sanofi Pasteur: Employee, Salary **A. Ozol-Godfrey**, Sanofi Pasteur: Employee and Shareholder, Salary **P. Tsang**, Sanofi Pasteur: Employee, Salary