AGENDA

The goal of today’s workshop is to discuss the appropriate target population for pharmacological therapy in celiac disease, and the definition and measurement of efficacy in celiac disease clinical trials intended to support marketing approval, including the role and timing of assessment of specific endpoints.

8:00 a.m. Opening Remarks

Donna Griebel/Andrew Mulberg

8:10 a.m. Session 1: Defining target patient population(s) for pharmacological therapies

Moderators: Sheila Crowe + Andrew Mulberg

Current management of celiac disease and identifying an appropriate patient population(s) for pharmacologic therapies in adult patients

Joseph Murray

Current management of celiac disease and identifying an appropriate patient population(s) for pharmacologic therapies in pediatric patients

Alessio Fasano

8:40 a.m. Panel Discussion

Panel: Joe Murray, Alessio Fasano, Sonia Kupfer, Alice Bast, Juli Tomaino, George Dukes, Ritu Verma

(40 min)

9:20 a.m. Public Q & A

(30 min)

9:50 a.m. Break

(20 min)

10:10 a.m. Session 2: Defining clinical benefit in celiac disease trials intended to support marketing approval

Moderators: Sonia Kupfer + Juli Tomaino
AGENDA

Patient’s perspective on a clinically meaningful benefit

Alice Bast

(10 min)
FDA White Oak Campus, Building 31, the Great Room
White Oak Conference Center, Silver Spring, Maryland
March 31, 2015

AGENDA

10:55 a.m. Panel Discussion  Panel: Sheila Crowe, Anthony DiMarino, Alice Bast, Ivor Hill, Stefano Guandalini, Ciaran Kelly, Donna Griebel, Jessica Lee, George Dukes

11:35 a.m. Public Q & A

12:10 p.m. Lunch

1:10 p.m. Session 3: Measuring clinical benefit in celiac disease trials intended to support marketing approval

Clinical outcome assessments to demonstrate clinical benefit  Elektra Papadopoulos

Role of histology to measure clinical benefit and appropriate timing of assessment(s)  Benjamin Lebwohl

Role of serology to measure clinical benefit and appropriate timing of...  Daniel Leffler
AGENDA

3:25 p.m.     Break     (15 min)

3:40 p.m.     Public Q & A     (40 min)

4:20 p.m.     Closing Comments     Juli Tomaino

4:30 p.m.     Adjournment