

Benchmark Activity 29.1:

The local health department shall develop and implement policies ensuring that state and federal requirements are followed regarding the rights of participants in local public health research programs and requiring that any requests to access health department clients have Institution Review Board approval obtained by the host research organization

**Durham County Board of Health
Agenda Item Summary**

Meeting Date: February 12, 2015

Agenda Item Subject: A Randomized, Phase 2 Study to Evaluate the Efficacy and Safety of AZD0914 in the Treatment of Male and Female Subjects with Gonorrhea

Attachment (s): Protocol Summary

Staff or Board Member Reporting: Arlene C. Sena, MD, MPH

Purpose: Action
 Information only
 X Information with possible action

Objectives:

To review a new research study sponsored by the National Institutes of Health to be conducted in the DCoDPH STD Clinic by UNC-CH research staff, titled “DMID 14-0014 - A Randomized, Open-label Phase 2 Study to Evaluate the Efficacy and Safety of a Single Dose of Oral AZD0914 Compared to Intramuscular Ceftriaxone in the Treatment of Male and Female Subjects with Uncomplicated Gonorrhea.”

Summary Information:

Uncomplicated gonorrhea is currently the second most common bacterial sexually transmitted infection (STI) worldwide and, accordingly, is a serious public health problem. *Neisseria gonorrhoeae* has demonstrated the ability to develop resistance to antimicrobial treatment used for management of uncomplicated gonorrhea. The CDC released its report Antibiotic Resistance Threats in the United States, 2013, which ranks drug-resistant *N. gonorrhoeae* as an “Urgent Threat.” Resistance of *N. gonorrhoeae* to macrolides (including azithromycin), cefixime, and ceftriaxone (used in most STD clinics) and subsequent clinical failures have been reported. The availability of an effective and well-tolerated oral agent able to be administered alone or in

combination for treatment of uncomplicated gonococcal infection caused by isolates with resistance to currently available first-line agents would satisfy an unmet need and potentially reduce the dissemination of multidrug-resistant *N. gonorrhoeae*.

AZD0914 is a spiropyrimidinetrione antibiotic with a novel mode of action being developed to help fill this need. AZD0914 has recently completed a Phase 1 multipart study (NCT01929629) in healthy adult volunteers. AZD0914 was well tolerated with transient taste disturbance and headache being the most commonly reported adverse events. The planned Phase 2 study will examine the efficacy of treating uncomplicated gonorrhea with 2 different doses of AZD0914 compared to treatment with single dose ceftriaxone. The primary endpoint will be the bacterial eradication, as measured by conversion from positive *N. gonorrhoeae* baseline urethral or cervical culture to negative at 6±2 days after treatment.

The study will recruit men and women ≥ 18 years of age with presumptive or confirmed gonorrhea, or sexual contact with a person with gonorrhea in the past 2 weeks. Study participants will have additional specimens for gonorrhea testing, and will be randomized to receive either ceftriaxone or study drug. Subjects will be followed for adverse events, and asked to return for a test of cure.

The resources to be requested from DCoDPH include:

- 1) referral from STD clinicians regarding potentially eligible patients with gonorrhea or contact to gonorrhea;
- 2) phlebotomy assistance;
- 3) space for recruitment, enrollment, follow-up, storage of study drug, and gonorrhea cultures.

Recommended Action:

- _____ Approve
- _____ Approve & forward to Board of Commissioners for action
- _____ Approve & forward to _____
- _____ Accept as information
- _____ Revise & schedule for future action
- _____ Other (details): _____