Solithromycin, a new chemical entity under development by Cempra Pharmaceuticals, is a fourth-generation macrolide antibiotic. The chemical structure of solithromycin is illustrated in Figure 1 below.

**Introduction and Purpose**

Solithromycin is currently entering Phase 3 of clinical development for the treatment of community-acquired bacterial pneumonia in adults. As part of Cempra’s Pediatric Development Plan, the company aims to identify development articles for a pediatric dosage formulation of solithromycin. The development of a taste masked solithromycin powder for oral suspension was conducted in collaboration with FlavorTech, Inc. to improve pediatric compliance of the drug due to its bitter taste. The overall goal was to enhance taste acceptance and reduce the bitterness. A taste masked formulation is one that is used to improve pediatric compliance of bitter drug, such as solithromycin, through the use of taste modulators in combination with the active ingredient. Based on the lingering bitterness profile, it was clear that high intensity sweeteners would be needed. Several options were evaluated in the developmental stages (1). All macrolides, including clarithromycin, have a bitter taste that must be masked in order to improve pediatric compliance. An iterative approach was used to evaluate the effects of various sweeteners and other formulation variables on flavor quality. The primary objective was to develop a taste masked solithromycin formulation suitable for children.

**Methods**

The development of a taste masked solithromycin powder for oral suspension was conducted by FlavorTech, Inc. in Lawrence, MA. Thirty-eight FlavorTech panelists (ages 18–49) were used to evaluate the formulations for sweetness and bitterness. The FlavorTech panelists were used to evaluate the formulations for sweetness and bitterness. The panelists recited their individual results and a preliminary Flavor Profile was developed. The panelists were then independently evaluated and recorded the aftertaste characteristics. The panelists were then independently evaluated and recorded the aftertaste characteristics. The results are summarized in Table 2 below.

**Results Continued**

Each sweetener (e.g. sucrose, sorbitol, and fructose) in combination with high intensity sweeteners would be needed. Several options were evaluated in the developmental stages (1). All macrolides, including clarithromycin, have a bitter taste that must be masked in order to improve pediatric compliance. An iterative approach was used to evaluate the effects of various sweeteners and other formulation variables on flavor quality. The primary objective was to develop a taste masked solithromycin formulation suitable for children.

**Conclusions**

Solithromycin (MAGNAMUS™) is a new chemical entity under development by Cempra Pharmaceuticals. The chemical structure of solithromycin is illustrated in Figure 1 below.