Introduction and aims: INT131 is a validated clinical target for addressing insulin resistance, a key etiologic factor in type 2 diabetes mellitus (T2DM). However, full activation of PPARγ by agents such as troglitazone and pioglitazone, which is the basis for the drug class, is associated with some undesirable effects. Consequently, there is a need for novel agents that activate the PPARγ receptor with fewer side effects for the treatment of T2DM.

Materials and methods: The safety profile of INT131 besylate was characterized in long-term studies in rodents and nonclinical chronic studies in monkeys. INT131 besylate was well tolerated in monkeys up to the highest dose, with no alterations in hematocrit and no evidence of safety issues in nonclinical studies. No effects were noted in the rodent studies.

Results: INT131 besylate treatment resulted in no changes in relative heart weight in monkeys, with no alterations in cardiac structure. No changes in echocardiography were noted in monkeys, with no changes in cardiac function in any of the INT131 doses tested.

Discussion: The rodent studies showed no changes in heart weight or echocardiography, with no effects on cardiac function in any of the INT131 doses tested. The results of the nonclinical studies indicate that INT131 besylate is a safe and effective insulin sensitizer for the treatment of T2DM.

Conclusion: INT131 besylate is a validated clinical target for addressing insulin resistance, a key etiologic factor in type 2 diabetes mellitus (T2DM). No changes were noted in heart weight or echocardiography in any of the INT131 doses tested. The results of the nonclinical studies indicate that INT131 besylate is a safe and effective insulin sensitizer for the treatment of T2DM. INT131 besylate is a novel, selective PPARγ agonist that has demonstrated safety and efficacy in nonclinical studies, with no changes in heart weight or echocardiography in any of the INT131 doses tested. The results of the nonclinical studies indicate that INT131 besylate is a safe and effective insulin sensitizer for the treatment of T2DM.