

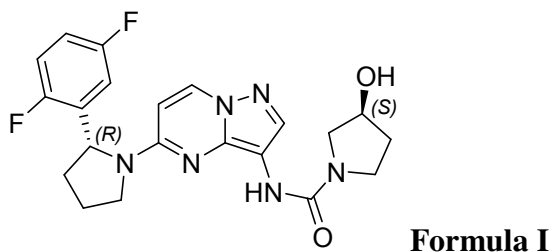
compound of Formula I. The compound may also be prepared as disclosed in US Application Ser. No. 14/943,014, filed November 16, 2015, incorporated by reference herein in its entirety.

- 5 There exists a need for alternative synthetic procedures for the preparation of the compound of Formula I. Such alternative synthetic procedures are disclosed herein.

SUMMARY

In one aspect, provided herein is a process for preparing a compound of Formula I

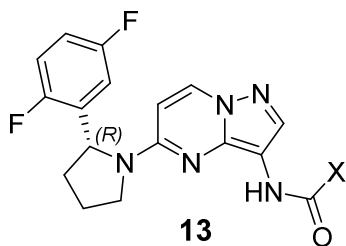
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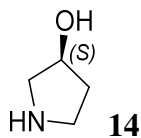
or a salt thereof,
comprising:

- (a) treating a compound of formula **13**

15



or a salt thereof with a compound of formula **14**



- 20 or a salt thereof to form a compound of Formula I;

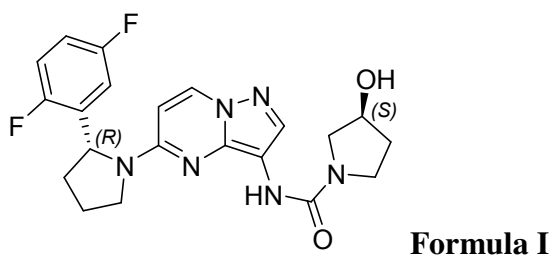
and

(b) optionally forming a salt of the compound of Formula I;

wherein X is halogen, C₁-C₆ alkoxy, C₆-C₁₀ aryloxy or a 5-membered heteroaryl containing at least one nitrogen directly bonded to the C=O of the compound of formula **13**, each

5 optionally substituted with one or more substituents independently selected from the group consisting of C₁-C₆ alkyl, C₁-C₆ haloalkyl, halogen, CN, OH, C₁-C₆ alkoxy, and NR¹R², where R¹ and R² are each independently selected from hydrogen and C₁-C₆ alkyl.

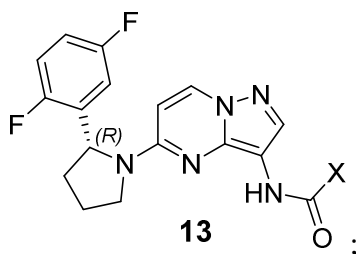
In one aspect, provided herein is a process for preparing a compound of Formula I



or a salt thereof,

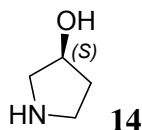
comprising:

(a) isolating a compound of formula **13**



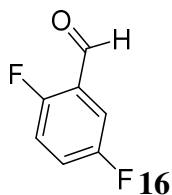
15 (b) optionally forming a salt of formula **13**;

(c) treating the compound of formula **13** or a salt thereof with a compound of formula **14**



or a salt thereof to form a compound of Formula I;

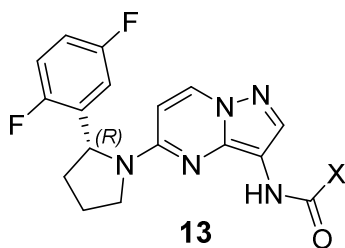
20 and



with (R)-2-methylpropane-2-sulfinamide,
to form a compound of formula **17**.

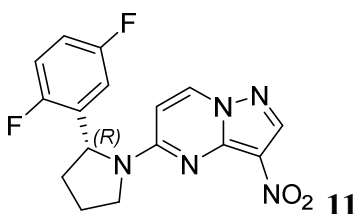
In one aspect, provided herein is a process for preparing a pharmaceutical
composition, comprising mixing (i) a compound of **Formula I** or salt thereof prepared
according to any of the processes described herein, and (ii) a pharmaceutically acceptable
carrier, to form the composition.

In one aspect, provided herein is a process for preparing a compound of formula **13**



or a salt thereof by a process comprising

a) treating a compound of formula **11**



or a salt thereof with a nitro reduction system to form a first mixture;
and

b) treating the first mixture with XC(O)Z to form a compound of formula **13** or a salt
thereof,

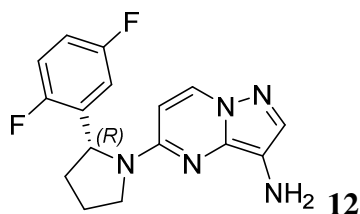
wherein X is halogen, C₁-C₆ alkoxy, C₆-C₁₀ aryloxy or a 5-membered heteroaryl containing at least one nitrogen directly bonded to the C=O of the compound of formula **13**, each optionally substituted with one or more substituents independently selected from the group consisting of C₁-C₆ alkyl, C₁-C₆ haloalkyl, halogen, CN, OH, C₁-C₆ alkoxy, and NR¹R²,

- 5 where R¹ and R² are each independently selected from hydrogen and C₁-C₆ alkyl; and wherein Z is a leaving group selected from halogen, C₁-C₆ alkoxy, C₆-C₁₀ aryloxy and a 5-membered heteroaryl containing at least one nitrogen directly bonded to the C=O of XC(O)Z, each optionally substituted with one or more substituents independently selected from the group consisting of C₁-C₆ alkyl, C₁-C₆ haloalkyl, halogen, CN, OH, C₁-C₆ alkoxy, and NR⁵R⁶, where R⁵ and R⁶ are each independently selected from hydrogen and C₁-C₆ alkyl;

provided that if Z is optionally substituted C₁-C₆ alkoxy, optionally substituted C₆-C₁₀ aryloxy, or optionally substituted 5-membered heteroaryl, then Z and X are the same.

- 15 In some embodiments, provided herein is a process for preparing a compound of formula **13** or a salt thereof comprising

- a) isolating a compound of formula **12**

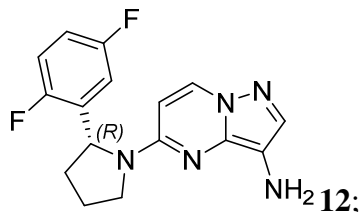


or a salt thereof;

- 20 b) treating a compound of formula **12** with XC(O)Z to form a compound of formula **13** or a salt thereof; and
c) optionally isolating the compound of formula **13**.

In one aspect, provided herein is a process for preparing a compound of formula **13** or a salt thereof comprising

- a) isolating a compound of formula **12**



b) treating a compound of formula **12** with XC(O)Z to form a compound of formula **13** or a salt thereof; and

c) optionally isolating the compound of formula **13**,

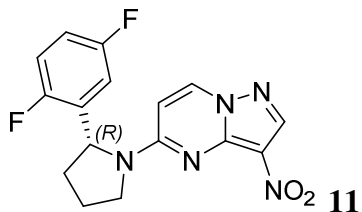
5 wherein X is halogen, $\text{C}_1\text{-C}_6$ alkoxy, $\text{C}_6\text{-C}_{10}$ aryloxy or a 5-membered heteroaryl containing at least one nitrogen directly bonded to the C=O of the compound of formula 13, each optionally substituted with one or more substituents independently selected from the group consisting of $\text{C}_1\text{-C}_6$ alkyl, $\text{C}_1\text{-C}_6$ haloalkyl, halogen, CN, OH, $\text{C}_1\text{-C}_6$ alkoxy, and NR^1R^2 , where R^1 and R^2 are each independently selected from hydrogen and $\text{C}_1\text{-C}_6$ alkyl,
10 and

 wherein Z is a leaving group selected from halogen, $\text{C}_1\text{-C}_6$ alkoxy, $\text{C}_6\text{-C}_{10}$ aryloxy and a 5-membered heteroaryl containing at least one nitrogen directly bonded to the C=O of XC(O)Z , each optionally substituted with one or more substituents independently selected from the group consisting of $\text{C}_1\text{-C}_6$ alkyl, $\text{C}_1\text{-C}_6$ haloalkyl, halogen, CN, OH, $\text{C}_1\text{-C}_6$ alkoxy,
15 and NR^5R^6 , where R^5 and R^6 are each independently selected from hydrogen and $\text{C}_1\text{-C}_6$ alkyl;

 provided that if Z is optionally substituted $\text{C}_1\text{-C}_6$ alkoxy, optionally substituted $\text{C}_6\text{-C}_{10}$ aryloxy, or optionally substituted 5-membered heteroaryl, then Z and X are the same.

 In one aspect, provided herein is a process for preparing a compound of formula **12**
20 or a salt thereof comprising

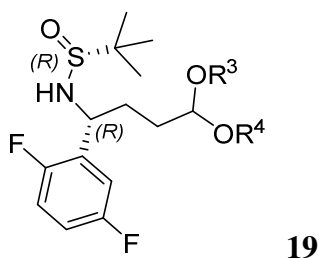
a) treating a compound of formula **11**



with a nitro reduction system to form the compound of formula **12** or a salt thereof;
and

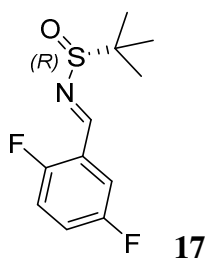
b) isolating the compound of formula **12** or a salt thereof.

- 5 In one aspect, provided herein is a process for preparing a compound of formula **10** or a salt thereof, comprising treating a compound of formula **19**

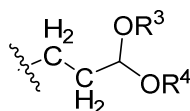


- 10 or a salt thereof, with an acid in the presence of a first reducing agent, to form a compound of formula **10** or a salt thereof.

In some embodiments, provided herein is a process for preparing a compound of formula **19** or a salt thereof, comprising treating a compound of formula **17**



- 15 with a reagent system comprising the group



to form a compound of formula **19**.