

!" #&/
4;O <548G=>3> 70AB>AC20==O ?@5?0@0BC

>@0=>
(LORANO® ODT)

!;:04 ;V:0@AL:>3> 70A>1C:

4VNG0 @5G>28=0: ;>@0B048=;

1 B01;5B:0 @0B048=C =V7>20=>3> 10 <3;

4>?>28=8: 0A?0@B0< (951), :8A;>B0 ;8<=>=0 1572>4=0, :@5<=VN 4V>:A84 :>;>W4=89 1572>4=89,
:@>E<0;L :C:C@C47O=89, ;0:B>70 1572>4=0, <03=VN AB50@0B, =0B@VN :@>A:0@<5;>70, <0=VB
(421), A>@1VB (420), :@>A?>2V4=>, :@5<=VN 4V>:A84 :>;>W4=89 2>4=89, ?>;VA>@10B, ?>2V4=>,
F5;N;>70 :@8AB0;VG=0, ?V4A>;>46C20G 0@><0B870B>@ 0?5;LA8=>289.

V:0@AL:0 D>@<0. "01;5B:8, I> 48A?5@3CNBLAO C @>B>2V9 ?>@>6=8=V.

V;>3> :>;L>@C :@C3;V, ?>A:V B01;5B:8.

0720 V 465==O 28@>1=8:0.

5: D0@<0F52B8G=0 :>25=VO/Lek Pharmaceuticals d. d., Slovenia.

5@>2H:>20, 57, 1526 N1;O=0, !;>25=VO/Verovskova, 57, 1526 Ljubljana, Slovenia.

\$0@<0:>B5@0?52B8G=0 3@C?0.

=B83VAB018 4;O A8AB5<=>3> 70AB>AC20==O. >4 " ! R06A X13.

>@0B048= 0=B83VAB0:0B>@ ?5@8D5@8G=8E 1-3VAB028E @5F5?B>@V2. @8 70AB>AC20==V C @5:>
<5=4>20=V9 4>7V =5 <0T ;V=VG=> 7=0GCI>W A540B82=>W B0 0=B8E>;V=5@3VG=>W 4VW. @>BO3>
< B@820;>3> ;V:C20==O =5 1C;> 28O2;5=> 6>4=8E ;V=VG=> 7=0GCI8E 7:07=8:0E 68BBT2> 206;828E
DC=:FV9, ;01>@0B>@=8E 4>A;V465==OE, 40=8E DV78:0;L=>3> >1AB565==O E2>@>3> 01> 2
5;5:B@>:0@4V>3@0@0B048= =5 <0T 7=0GCI>3> 2?;82C =0 0:B82=VABL2-3VAB028E @5F5?B>@V2, =5
1;>:CT 70E20B =>@5?V=5D@8=C B0 D0:B8G=> =5 2?;820T =0 A5@F52>-AC48==C A8AB5=0
0:B82=VABL 2>4VO @8B

VA;O ?5@>@0;L=>3> ?@89>@0B048= 4>1@5 2A<>:BCTBLAO B0 <5B01>;V7CTBLAO ?V4 2?;82><
CYP3A4 B0 CYP2D6 3>;>2=8< G8=>< C 457;>@0B048=. '0A 4>AO3=5==O <0:A8<0;L=>W
:>=F5=B@0FVW ;>@0B048=C B0 457;>@0B048=C C ?;072V AB0=>28BL 1-1,5 3>48=8 B0 1,5-3,7 3>48=8
2V4?>2V4=>. □2 O7C20==O ;>@0B048=C 7 1V;;<8 ?;07<8 :@>2V AB0=>28BL 97-99 %, 9>3>
<5B01>;VBC 73-76 %.

!5@54=V9 ?5@V>4 =0?V2282545==O C 74>@>28E ?0FVT=BV2 8,4 3>48=8 4;O ;>@0B048=C V 28 3>48=
4;O >A=>2=>3> <5B01>;VBC.

@81;87=> 40 % 22545=>W 4>78 282>48BLAO 7 A5G5N V 42 % 7 :0;< C?@>4>26 10 4=V2, 3>;>2=8<
G8=><, C D>@= N3>20=8E <5B01>;VBC. @81;87=> 27 % 22545=>W 4>78 282>48BLAO 7 A5G5N 70
?5@HV 24 3>48=8. 5=H5 1 % 0:B82=>W AC1AB0=FVW 282>48BLAO C =57@0B048= 01> 457;>@0B048=
V>4>ABC?=VABL ;>@0B048=C B0 457;>@0B048=C ?@O<> ?@>?>@FV9=0 4> 4>78.

@89>< W6V =57=0G=> ?>4>26CT G0A 2A<>:BC20==O ;>@0B048=C, 0;5 =5 2?;820T =0 ;V=VG=89
5D5:B.

?0FVT=BV2 7 E@>=VG=8<8 ?>@CH5==O<8 DC=:FVW =8@>: A5@54=V9 ?5@V>4 =0?V2282545==O
;>@0B048=C V 9>3> <5B01>;VBC ACBBT2> =5 2V4@V7=OTBLAO 2V4 B0:>3> 4;O 74>@>28E
?0FVT=BV2. # ?0FVT=BV2 7 E@>=VG=8<8 ?>@CH5==O<8 DC=:FVW =8@>: 35<>4V0;V7 =5 2?;820T =0
D0@<0>:V=5B8:C ;>@0B048=C B0 9>3> 0:B82=>3> <5B01>;VBC.

?0FVT=BV2 7 E@>=VG=8<8 70E2>@N20==O<8 ?5GV=:8 0;>3>;L=>W 5BV>;>3VW ?V:>2V @V2=V
:>=F5=B@0FVW ;>@0B048=C C ?;072V 7@>AB0NBL C42VGV, B>4V O: D0@<0>:V=5B8G=89
?@>DV;L 0:B82=>3> <5B01>;VBC ACBBT2> =5 2V4@V7=OTBLAO 2V4 B0:>3> 4;O ?0FVT=BV2 7 =>@
<0;L=>N DC=:FVTN ?5GV=:8. 5@V>4 =0?V2282545==O ;>@0B048=C B0 9>3> <5B01>;VBC AB0=>282
24 3>48=8 V 37 3>48= 2V4?>2V4=> B0 71V;LHC202AO 70;56=> 2V4 B06:>ABV 70E2>@N20==O
?5GV=:8.

>:070==O 4;O 70AB>AC20==O.

!8<0B8G=5 ;V:C20==O 0;5@3VG=>3> @8=VBC B0 E@>=VG=>W V4V>?0B8G=>W :@>?82O=:8.

@>B8?>:070==O.

@5?0@0B ?@>B8?>:070=89 ?0FVT=B0< 7 ?V428I5=>N GCB;82VABN 4> 0:B82=>W @5G>28=8 01>4> 1C4L-O:>3> V=H>3> :>=5=B0 ?@5?0@0BC.

0;56=V 70E>48 157?5:8 ?@8 70AB>AC20==V.

0FVT=B0< V7 BO6:8< ?>@CH5==O< DC=:FV9 ?5GV=:8 =5>1EV4=> ?@87=0G0B8 <5=HC ?>G0B:>2C 4>7C G5@57 <>6;825 7<5=H5==O ;V@5=AC ;>@0B048=C (@5:><5=4>20=0 ?>G0B:>20 4>70 10 <3 G5@57 45=L). "5@0?VN >@0=> " A;V4 ?@8?8=8B8 ?@8 28=8:=5==V 0;5@3VG=>W @50:FVW 01> BO6:8E ?>1VG=8E 5D5:BV2.

0AB>AC20==O ?@5?0@0BC =5>1EV4=> ?@8?8=8B8, O:

@5?0@0B 7C V A>@1VB, B>3> =5 A;V4 ?@87=0G0B8 ?0FVT=B0< 7 @V4:VA=8<8 A?04:>28<8 D>@<0 <8 =5?5@5=>A8<>ABV D@C:B>78 B0 30;0:B>78, 45DVF8B>< ;0:B078 01> A8=4@>>< 3;N:>7> 30;0:B>7=>W <0;L01A>@1FVW.

@5?0@0B

A>1;82V 70AB5@565==O.

0AB>AC20==O C ?5@V>4 203VB=>ABV 01> 3>4C20==O 3@C44N.

57?5:0 70AB>AC20==O ;>@0B048=C 203VB=8< =5 2AB0=>2;5=0, B><5=4CTBLAO ?@87=0G0B8 >@0=> " C ?5@V>4 203VB=>ABV.

>@0B048= ?@>=8:0T C 3@C4=5 <>;>:, B><5=4CTBLAO 70AB>A>2C20B8 ?@5?0@0B C ?5@V>4 3>4C20==O 3@C44N.

\$5@B8;L=VABL. 0=V I>4> ??:82C ?@>4C:BC =0 6V=>GC 01> G>;>2VGC D5@B8;L=VABL 2V4ACB=V

40B=VABL ??:820B8 =0 H284:VABL @50:FVW ?@8 :5@C20==V 02B>B@0=A?>@B< 01> @>1>BV 7 V=H8<8 <5E0=V7<0<8.

;V=VG=8E 4>A;V465==OE =5 2V47=0G02AO ??:82 ?@5?0@0BC =0 H284:VABL @50:FVW ?0FVT=B0. @>B5 ?0FVT=B <0T 1CB8 ?@>V=D>@<>20=89 ?@> >:@5=;82>ABV 01> 70?0<>@>G5==O, O:V <>6CBL ??:820B8 =0 740B=VABL :5@C20B8 02B>B@0=A?>@B< 01> ?@0FN20B8 7 V=H8<8 <5E0=V7<0<8.

VB8.

D5:B82=VABL B0 157?5:0 70AB>AC20==O ?@5?0@0BC 4VBO< 2V:>< 4> 2 @>:V2 =5 2AB0=>2;5=0.

!>AV1 70AB>AC20==O B0 4>78.

"01;5B:8 <>6=0 70AB>A>2C20B8 =570;56=> 2V4 ?@89>AC20==V B01;5B>: A;V4 4>B@815@56=>ABV V 1@0B8 WE BV;L:8 ACE8<8 @C:0<8.

"01;5B:C A;V4 ?>:;0AB8 =0 O78: V 70G5:0B8, 4>:8 2>=0 ?>2=VABN @>7G8=8BLAO, 70?820B8 B01;5B:8 2>4>N 01> V=H>N @V48=>N =5 B@510.

>@>A;8< V 4VBO< 2V4 12 @>:V2 ?@87=0G0B8 ?> 10 <3 ;>@0B048=C (1 B01;5B:0) 1 @07 =0 4>1C. VBO< 4> 12 @>:V2 7 <0A>N BV;0 IV;LH5 30 :3 ?@87=0G0B8 ?> 10 <3 (1 B01;5B:0) 1 @07 =0 4>1C.

"01;5B:8 ?> 10 <3 =5 70AB>A>2C20B8 4VBO< 7 <0A>N BV;0 <5=H5 30 :3. "0:8< ?0FVT=B0< @5:> <5=4CTBLAO 70AB>A>2C20B8 ?@5?0@0B C 283;04V A8@>?C 01> ACA?5=7VW.

0FVT=B0< 7 BO6:8< ?>@CH5==O< DC=:FVW ?5GV=:8 A;V4 ?@89<0B8 <5=HC ?>G0B:>2C 4>7C ?@5?0@0BC, >A:V;L:8 ;V@5=A ;>@0B048=C C E2>@8E FVTW 3@C?8<>65 7=86C20B8AO. ;O 4>@>A;8E V 4VB59 7 <0A>N BV;0 ?>=04 30 :3 @5:><5=4CTBLAO ?@89>< 10 <3 ;>@0B048=C G5@57 45=L.

0FVT=B0< ;VB=L>3> 2V:C B0 E2>@8< V7 =8@:>2>N =54>AB0B=VABN :>@5:FVO 4>78 =5 ?>B@V1=0.

5@54>7C20==O.

5@54>7C20==O ;>@0B048=C ?V428ICT G0AB>BC 28=8:=5==O 0=B8E>;V=5@3VG=8E A87C20==V
 2V47=0G0;8AO A>;82VABL, B0EV:0@4VO B0 3>;>2=89 1V;L. @8 ?5@54>7C20==V @5:×5=4CTBLAO
 A8<0B8G=5 B0 ?V4B@8C?@>4>26 =5>1EV4=>3> ?5@V>4C G0AC. 5:×5=4CNBLAO AB0=40@B=V
 70E>48 I>4> 2840;5==O ?@5?0@0BC, O:89 =5 2A<:B02AO 7V H;C=:0: ?@><820==O H;C=:0, ?@89><
 ?>4@V1=5=>3> 0:B82>20=>3> 2C3V;;O 7 2>4>N.
 >@0B048= =5 282>48BLAO H;OE× 35<>4V0;V7C; =52V4><>, G8 282>48BLAO ;>@0B048= H;OE×
 ?5@8B>=50;L=>3> 4V0;V7C.
 VA;O =52V4.;04=>W 4>?>>38 ?0FVT=B <0T 70;8H0B8AO ?V4 <548G=8< =03;O4>

>1VG=V 5D5:B8.

4VB59 2V:× 2V4 2 4> 12 @>:V2 2V47=0G0;8AO B0:V =51060=V O28I0 O: 3>;>2=89 1V;L,
 =5@2>7=VABL 01> ?V428I5=0 2B×;N20=VABL. # 4>@>A;8E B0 4VB59 2V:× 2V4 12 @>:V2
 2V47=0G0;8AO A>;82VABL, 3>;>2=89 1V;L, ?V428I5=89 0?5B8B B0 157A>==O.
 !?>AB5@V30;8AO ?>>48=>:V 28?04:8 =0ABC?=8E ?>1VG=8E 5D5:BV2:

!8AB5<8 >@30=V2	>1VG=V 5D5:B8
	=0DV;0:AVO
5@2>20 A8AB5<0	0?0<>@>G5==O. AC4×<8
!5@F52>-AC48==0 A8AB5<0	"0EV:0@4VO, 2V4GCBBO A5@F518BBO, ?0;L?VB0FVO.
(;C=:>2>-.8H:>289 B@0:B	C4>B0, ACEVABL C @>BV, 30AB@8B
5?0B>1V;V0@=0 A8AB5<0	>@CH5==O ?5GV=:>28E DC=:FV9
(:V@0 B0 ?V4H:V@=0 B:0=8=0	8A8?0==O, 0;>?5FVO
030;L=V ?@>O28	V428I5=0 2B><;N20=VABL

70T<>4VO 7 V=H8<8 ;V:0@AL:8<8 70A>10<8 B0 V=HV 2848 270T<>4V9.

@5?0@0B =5 ?>A8;NT ?@83=VGC20;L=C 4VN 0;:>3>;N =0 ?A8E><>B>@=V @50:FVW.
 4=>G0A=5 70AB>AC20==O ;>@0B048=C 7 V=3V1VB>@0<8 CYP3A4 01> CYP2D6 <>65 ?@872>48B8 4>
 ?V428I5==O @V2=O ;>@0B048=C, I>, C A2>N G5@3C, ?>A8;NT ?>1VG=V 5D5:B8.
 @8 >4=>G0A=>AC20==V ;>@0B048=C 7 :5B>:=>07>;<, 5@8B@<, F8<5B848=>< 2V47=0G0;>AO
 ?V428I5==O :=F5=B@0FVW ;>@0B048=C C ?;072V, 0;5 F5 ?V428I5==O =5 28O2;O;>AO ;:V=VG=>, C B>
 VB8. >A;V465==O 270T<>4V9 7 V=H8<8 ?@5?0@0B0<8 ?@>2>48;8AO BV;L:8 7 CG0ABN 4>@>A;8E
 ?0FVT=HV2.

"5@ABV.3 @>:8.

#<>28 715@V30==O.

15@V30B8 2 >@83V=0;L=V9 C?0:>2FV.
 15@V30B8 C =54>ABC?=>

#?0:>2:0. > 7 01> 10 B01;5B>: C 1;VAB5@V; ?> 1 (7□ 1) 01> 2 (10□ 2) 1;VAB5@8 C :0@B>==V9 :=@>1FV.

0B53>@VO 2V4?CA:C. 57 @5F5?B0.